THE STRUGGLE FOR ACCESS TO TREATMENT FOR HIV/AIDS IN INDIA

Dipika Jain & Rachel Stephens

HRLN
Human Rights Law Network

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The Struggle for Access to Treatment for HIV/AIDS in India

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Foreword

The most conservative estimates say that around 25 lakh (2.5 million) people are living in India with HIV/AIDS. Of these, as of 30 June 2008, government figures report that only 156,403 people are receiving free anti-retroviral therapy. This, according to UNAIDS figures, is fewer than 20% of those in need of treatment. This compares abysmally to countries such as South Africa which has achieved 42% coverage, Thailand which has 52.9% and Brazil, which has achieved 94.8%.

Despite ferocious pressure placed on the Government of India by civil society groups, the Government responded very slowly to the demand for treatment, instead focusing its attention, advocacy and budget almost exclusively on prevention efforts. This had two catastrophic effects. Most basically, it prevented people who required treatment to prolong and improve their lives from receiving it. It is not known how many people died as a result of this Government policy, as no records have been kept of deaths due to AIDS in India. What is clear is that many lives were lost, and continue to be lost, simply due to the fact the Government of India refused for too long to make treatment available.

The second disastrous, although more subtle, impact of the Government's refusal to acknowledge the need to provide treatment was the impact this had on stigma and discrimination towards PLHA and the framing of the dialogue around tackling the epidemic in a rights-based structure. With emphasis placed on methods of prevention, the dialogue centred on "high-risk" activities and groups of society, stigmatising these groups – commercial sex workers and injecting drug users, for example.

It also made people fearful to step forward and get themselves tested – there is very little incentive for a person to step forward and risk receiving a positive result when there is no treatment, and precious little counselling about nutrition, positive living etc., available.

These factors, together with prevalent reluctance in Indian society to discuss sex and sexuality, drug use etc., combine to drive those people who have stepped up and tested positive underground, rather than face daily discrimination.

In 2001, a public interest litigation was filed on behalf of the Voluntary Health Association of Punjab. This piece of litigation called on the Government of India to provide adequate treatment for those in need, as well as to provide other economic and social support. This litigation has put enormous pressure on the Government of India to provide treatment for people living with HIV/AIDS and, in 2004, a limited roll out of first line anti-retroviral treatment began. Significant improvements have been seen in the years since. However, anti-retroviral drugs are like antibiotics, in that the virus inside a person develops resistance to them, and the person has to take more sophisticated drugs. These more sophisticated drugs are called second line anti-retrovirals, and the Government of India has only just started providing these, on an extremely limited basis, to a restricted number of people in two centres in Chennai and Mumbai in 2008 on a "pilot" basis. A planned phase-up of this programme has been beset by predictable and preventable obstacles that the Government appears unwilling, or unable, to resolve.

Civil society, networks of positive people and international agencies continue to apply pressure to the Government of India, through the National AIDS Control Organisation, to rapidly scale up its treatment programme, before more lives are unnecessarily lost. This book attempts to document the struggle that has been faced by those requiring treatment, and those affected by HIV/AIDS since the first recorded incidence of HIV/AIDS in India in 1986. It is presented in the fervent hope that universal access to treatment as a human right is a realistic prospect for all those desperately in need.

Glossary

Adherence: Closely following and adhering to a prescribed treatment regime, including taking the correct dose of the correct drug at the correct time. This is particularly important when taking ARV drugs

AIDS: Acquired Immunodeficiency Syndrome

Anti-retroviral treatment or therapy: Drug treatment which, when taken properly, significantly increases the expected life-span of a PLHA.

ARV Treatment or Therapy: Anti-retroviral treatment or therapy

CD4 cell: Also known as a helper T-cell or CD4 lymphocyte. It is a white blood cell that fights infection. CD4 cells coordinate the immune response, signalling other cells in the immune system to perform their special functions. The number of CD4 cells in a sample of blood is an indicator of the health of the immune system.

CSW: Commercial sex worker(s)

GIPA: Greater Involvement of People Living with HIV/AIDS

Global Fund: Global Fund to Fight AIDS, Tuberculosis and Malaria

HIV: Human Immunodeficiency Virus

MSM: Men who have sex with men, or a man who has sex with men

NACO: National AIDS Control Organisation

NACP: National AIDS Control Programme, a phased programme, of which Phase III was announced in July 2007

OI: Opportunistic infection; an infection contracted by a PLHA to which he or she is more susceptible as a result of his or her weakened immune system

PEPFAR: [United States] President's Emergency Plan for AIDS Relief

PLHA/PLWHA: Person (or people) living with HIV/AIDS

Provider-initiated testing: A policy under which healthcare providers recommend to patients presenting with symptoms indicating HIV that they be tested for HIV.

(P)PTCT: (Prevention of) Parent to child transmission, referring to transmission of HIV from mother to child before or during birth, or through breast feeding

Section 377: Section 377 of the Indian Penal Code, which as currently interpreted criminalises sex between same sex partners

SACS: State AIDS Control Organisations, the state-level governmental bodies charged with providing for prevention, treatment and care relating to HIV/AIDS

TB: Tuberculosis

VCTC: Voluntary Counselling and Testing Centre

WHO: World Health Organisation

CHAPTER 1

Introduction

Since the appearance of HIV in the early 1980s, the campaign against the HIV/AIDS epidemic has undergone a revolutionary transformation. With the emergence of HIV/AIDS as a human rights issue, attitudes towards HIV/AIDS have become increasingly more humanised and individually-focused as the infection loses its aura of mystery, blame and swift lethality in many parts of the world. These changes can be credited largely to the emergence of highly active antiretroviral therapy (HAART), also known as antiretroviral drugs (ARVs), antiretroviral therapy (ART) or, more recently, potent combination antiretroviral therapy. By directly attacking HIV replication in the body, ARV drugs reduce levels of HIV in the body, ultimately slowing and preventing damage to the immune system. The introduction of ARV drugs in conjunction with supportive medical care, testing and treatment, which together comprise ART, has resulted in a decrease in the incidence of AIDS, opportunistic infections and AIDS-related mortality by 60-80%.[1] A person living with HIV/AIDS ("PLHA") treated with ART can live a longer and healthier life than one who is not treated with ART. Such treatment can even bring patients back from clinical AIDS stages of the virus into good health.[2]

However effective, ART is not a cure for HIV; it is treatment for improving the health and prolonging the lives of those living with HIV/AIDS. With the success of ART, PLHA have at least been offered the "option" of living with a chronic, but fairly stable illness, as opposed to dying without treatment. Without ART, this option is removed for PLHA.

National pilot programmes for ARV provision in low and middle income countries such as Argentina, Brazil, Chile, Thailand, Cote d'Ivoire,

1 http://ymtdl.med.yale.edu/theses/available/etd-06282006-140012/restricted/Rajkumar_HIV_Testing_Paper_Binding_Copy.pdf

2 *Antiretroviral (ARV) Treatment Fact Sheet 02*, International HIV/AIDS Alliance, March 2005. http://www.aidsalliance.org/custom_asp/publications/view.asp?publication_id=182&language=en

Senegal, and Uganda have shown that large-scale distribution of ARV drugs is generally as feasible and effective as in high-income countries.[3] Other Governments have made similar commitments towards Government-supported ARV provision (although not necessarily universal), including Tunisia, Zimbabwe, Malawi, Taiwan, Canada, Denmark, Finland, Cuba, Mexico, Mauritius, Jamaica, and South Africa.[4]

These programmes have demonstrated that the cost of drug provision is offset by reductions in treatment required for opportunistic infections ("OIs"), the consequent reduced burden on state medical systems, increased economic productivity of PLHA, and a lower burden on social security and community networks.[5]

Universal access to ART is not a novel concept, nor should it be perceived as a luxury of wealthy Governments. In addition to moral, economic, and ethical issues, the lack of access to ART is recognised as constituting a human rights violation.[6] In light of this recognition that the human rights of PLHA must be upheld, and the concomitant necessity to provide universal access to ART, in 2003, the Government of India was pressurised to act accordingly through a Public Interest Litigation filed by the Human Rights Law Network ("HRLN") on behalf of the Voluntary Health Association of Punjab ("VHAP"), referred to as *Voluntary Health Association of Punjab* v *Union of India & Ors.*[7] Partly as a response to this Petition, the Government of India announced a roll out programme for free ART, starting on 1 April 2004. This seminal case will be discussed in much greater detail in later chapters.

In order to comprehend the desperate state of ART provision in India, it is imperative to study the science of ART and the background of the HIV/AIDS pandemic and its policy implications for HIV positive people in India.

Until 2004, the Government of India's response to the problems presented by HIV/AIDS had focused almost exclusively on prevention and not at all on treatment and care. This had devastating effects on those living

3 Shruti Pandey, *Fight for Free ARV Drugs*, Combat Law, vol. 5 issue 2, p. 11 April-May 2006.
4 Ibid.
5 Ibid.
6 Ibid., *PIL for Universal Access to ARVs*
7 Supreme Court of India, No. 311 of 2003

with HIV/AIDS, as it stifled their access to treatment and services, as well as increasing the stigma and discrimination they faced in all areas of their lives.

The Government's ARV treatment programme has failed to meet even its own goals, which have in themselves been inadequate. In response, the Government has denied it ever had these goals. In late 2003, the Union Minister for Health & Family Welfare, Smt. Sushma Swaraj, announced a Governmental policy for providing first line anti-retroviral treatment to 1,00,000 people living with HIV/AIDS, free of cost, with implementation starting on 1 April 2004.[8] The goal of the programme, as outlined in the Draft NACO Guidelines, was, "*[t]o place 1,00,000 people living with HIV/AIDS on structured ART by the end of 2005 and be able to provide treatment to additional of 15-20% of people living with HIV/AIDS each year, thereafter, for a period of five years.*"[9]

Although tragically late, this goal of 1,00,000 persons on treatment by the end of 2005 was a welcome and achievable goal set out by the Government. In July 2005, however, the new Minister for Health & Family Welfare, Smt. Panabaka Lakshmi inexplicably reported to parliament that the Government's goal had never been to treat 1,00,000 people by 2005, but rather to treat that number of people by December 2007. The Minister announced at the same time that only 10,255 patients were enrolled at that time in the rollout ARV hospitals.[10]

In the meantime, on World AIDS Day 2003, the WHO had begun its "3 by 5 Initiative", under which the goal was to ensure three million people living with HIV/AIDS would be receiving treatment by 2005. This initiative, and its target, were part of the WHO goal of making universal access to effective HIV/AIDS treatment available as a human right. In material submitted to and published by the WHO in the middle of 2005, the Government of India's declared target was to have 1,00,000 people on ART by the end of 2005.[11] This makes it all the more disappointing

8 http://www.icmr.tn.gov.in/news/yr2005/jun/news140605.pdf

9 The Draft 2004 NACO Guidelines "Programme Implementation Guidelines for a Phased Scale up of Access to Antiretroviral Therapy (ART) for People Living with HIV/AIDS (PLHA)" are no longer available from the NACO website – please contact HRLN for a copy

10 http://www.panossouthasia.org/pdf/Antiretrovirals.pdf; Lok Sabha unstarred question No. 454 to be answered on July 27, 2005.

11 http://www.who.int/3by5/support/june2005_ind.pdf

that the Government of India chose to ignore promises it had made in 2003 to ensure 1,00,000 people were on ART by the end of 2005.

By 2007 the Government had begun distributing free ARV drugs in 17 hospitals throughout India, starting to fulfil a promise it had made back in 2003. Such a slow roll out was never going to enable it to achieve its goal. The Government's treatment programme needed to be radically and quickly expanded to deal with the scale of the epidemic, and provide treatment in a comprehensive and reachable manner to all those who need it.

At the time of going to print, there are 172 ART centres operating throughout India providing first line ARV drugs free of cost, where supplies allow. NACO figures show that by March 2008, there were 1,34,000 people receiving first line treatment. The Government of India has thus far refused to provide second line treatment to those in need, other than those living nearby to two pilot-programme centres in Tambaram (Chennai) and Mumbai. This is issue is further discussed in Chapter 6. Further information about the actual state of the Government's ART roll out is set out in Chapter 6.

CHAPTER 2

The science of antiretroviral treatment

The Virus and Viral Load

HIV is a virus and, like any other virus, is an infection in the body which attacks a part of the body. In the case of HIV, the virus attacks the body's immune system, specifically the CD4 cells[12] which play a crucial role in supporting the body's immune system. An untreated PLHA may have thousands or even millions of HIV particles in every millilitre of his or her blood. This is known as the "viral load." The lower the viral load, the better the person's immune system can recover. The aim of ART is to suppress the level of HIV in the body to very low levels, ideally below 50 copies of HIV per millilitre of blood (50/mm^3). A viral load as low as 50/mm^3 or below is generally referred to as "undetectable." Without HIV interference in CD4 reproduction (required for the proper functioning of the body's immune system), the CD4 cells and the immune system will be able to recover and regain the ability to fight off infection. With a decreased viral load and increased CD4 count, PLHA can regain their health and extend their lives.

"Undetectable" levels of HIV do not mean a person is no longer HIV positive, nor does it mean that he or she cannot transmit the virus to others. People with "undetectable" levels of HIV are still positive, and must take all the precautions with regard to their own well-being and the well-being of others. Although a benefit of ART is that suppressed viral loads may reduce infectiousness, the evidence is currently inconclusive as to the actual effect on transmission rates.[13]

12 http://www.aidshealth.org/illnesses-and-treatments/hiv-aids/

13 Mead Over, Peter Heywood et al., *HIV/AIDS Treatment and Prevention in India: Modeling the Cost and Consequences*, The World Bank Human Development Network, Health, Nutrition, and Population Series, p. 20 , June 2004

HIV attacks a specific cell in the immune system called a T-helper or CD4 cell, which operates as a "defence system" against outside infections. Over time, HIV reduces the number of CD4 cells in the body, and weakens the immune system through its replication cycle. If CD4 cell destruction persists, the body is unable to fight even the simplest infections (known as opportunistic infections as they take advantage of the body's weakened immune system), resulting in AIDS.

The HIV life cycle follows a specific reproductive pathway. The cycle begins with contact between the virus and the CD4 cell, then to infection of the cell, and finally HIV replication through "commandeering" of the CD4 cell's reproductive mechanisms. The final result is death of the CD4 cell, and a large number of newly replicated HIV viruses. There are 5 basic stages to the life cycle of HIV that are relevant to ART. These are:

- ***Binding and Fusion:*** HIV binds to the CD4 cell and injects HIV genetic material into it.
- ***Reverse Transcription:*** CD4 cells copy the HIV genetic material.
- ***Integration:*** HIV's viral DNA is integrated into the CD4 cell's DNA.
- ***Transcription/Translation:*** The CD4 cell then produces HIV genetic material during its own reproductive processes.
- ***Viral Assembly:*** HIV, having reproduced its genetic material by commandeering the CD4 cell's reproductive machinery, breaks free of the CD4 cell and multiplies, which in the process causes the CD4 cell to rupture and die.

HIV is drawn to the CD4 cells because they have compatible receptors: CD4 receptors are a "lock" into which HIV's "keys" fit. After attaching itself to the cell, the virus injects its genetic material into the CD4 cell (Binding & Fusion). Once inside the CD4 cell, the HIV genetic material is inserted into the "blueprints" of the CD4 cell's reproductive and protein-producing processes (Reverse Transcription). The HIV DNA thus becomes integrated into the CD4 DNA, and can remain latent within the cell for many years (Integration).[14] As a result, during the

14 Rajesh Gandhi, M.D., et al., Life Cycle of HIV-Infection, John Hopkins AIDS Service, John Hopkins University Division of Infectious Diseases and AIDS Service. May 1999. http://www.instruction.greenriver.edu/kmarr/Biology%20201/Lecture%20Notes/Week%2011/hivcycle_Johns%20Hopkins.html

CD4 reproduction process, HIV proteins are made and thousands of new HIV particles are produced, instead of a new CD4 cell (Transcription/ Translation). Thus, in the process of cell division where an uninfected CD4 cell would normally produce more CD4 cells, the CD4 cell produces only HIV particles. As a result, the CD4 cell dies having produced only HIV instead of more CD4 cells (Viral Assembly).

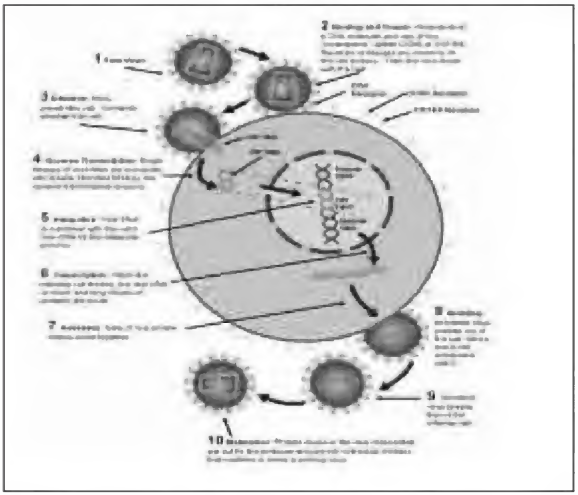
Types of ARV Drugs

There are five classes of existing antiretroviral drugs. (i) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI); (ii) Nucleotide Analogue Reverse Transcriptase Inhibitors (NtRTI); (iii) Nucleoside Analogue Reverse Transcriptase Inhibitors (NRTI); (iv) Protease Inhibitors; and (v) Fusion Inhibitors. These drugs specifically target a particular step of the HIV replication process to inhibit HIV reproduction: (1) NNRTIs, NtRTIs and NRTIs by inhibiting reverse transcription (transcriptase inhibitors) (point four in Figure 1); (2) protease inhibitors target viral assembly and prevent maturation of the HIV cell by inhibiting the protease enzyme from cutting protein chains into proteins (point 10 in Figure 1); (3) fusion inhibitors prevent HIV fusion with the CD4 receptors (point two in Figure 1); and (4) integrase inhibitors prevent the viral DNA from being inserted into the "blueprint" of the CD4 cell's protein factory. The aim of each type of ARV is to prevent the production of more HIV copies.

The different operation of each type of drug means that these drugs must be given in combination, commonly known as drug "cocktails." Attached at Annexures 1 to 3 is a list of those ARV drugs listed as available through the Government of India's roll out programme, together with a list of those ARV drugs currently recommended by the World Health Organisation. Combining different classes of medication simultaneously can hinder HIV reproduction at several points along the life cycle of the virus. Such combinations are the most effective way of reducing the viral load, because they suppress viral replication at multiple points. Therefore if one drug fails to block one process of HIV replication, the hope is that another drug will catch it at the next point. A combination of, for example, a reverse transcriptase inhibitor, a fusion inhibitor and a protease inhibitor sets up a series of obstacles to HIV reproduction which

the virus must overcome in order to reproduce. Resistance is avoided by targeting multiple steps at which replication is inhibited. Again, if a virus is resistant to two drugs, the hope is that the third may catch it. In essence, the multi-process approach lowers the ability of the virus to mutate and develop resistance. The complexity of such regimens requires that access to medication be consistent, correct, and of high quality. Failure to meet these rigorous standards amounts to failed treatment.

Figure 1



Complexities of ART and Strict Adherence Requirement

Guidelines for starting ART vary from region to region, depending mostly on economic circumstances and the availability of ARV drugs. In resource-poor countries such as India, ART is generally started when the patient's CD4 count drops below 200/mm^3, the immune threshold at which the Center for Disease Control (U.S.) recognises AIDS. In high-

income countries such as the United States of America and Western Europe, guidelines recommend beginning ART when an asymptomatic (i.e. not suffering from opportunistic infections) patient's CD4 count falls below 350/mm^3, although there is still active debate over whether treatment should begin earlier. In either case, treatment is suggested if the patient is symptomatic (that is, has developed one or more of certain opportunistic infections), is in a clinically advanced stage of HIV (i.e. has a serious co-infection such as tuberculosis), or has a high viral load (1,00,000/mm^3) together with a borderline CD4 count (350/mm^3).

ART is a life long commitment. With current medical technology, HIV cannot be eradicated and the latent HIV DNA "encoded" in the CD4 DNA ensures that HIV remains in the body even if retroviral particles are undetectable and inactive (i.e. when a person has a low viral load). Adherence is vital to effective treatment. Adherence means taking the drugs exactly as prescribed – on time and in accordance with any diet/ lifestyle restrictions, and for a person's lifetime.

There are two major problems associated with non-adherence: (i) failure of the drug to suppress HIV if not taken properly; and (ii) the development of drug resistance. If the drug treatment instructions are not followed, the drugs may not be absorbed properly in the body, and will essentially be wasted. The virus will not be suppressed and the drugs will provide no benefit to the individual, although the person taking the drugs may still get the negative side effects. Adherence levels of over 90-95% are needed to get the best response. This means missing *no more than one dose a month* for a regimen of daily therapy.

Strict adherence can be made difficult by the fact that ART regimens are rigorous and difficult for most patients due to the side effects of many of the medications, and the need for close monitoring and medical attention.

The second major problem is that HIV is an extremely adaptable virus that mutates and develops resistance to treatment quickly. HIV can replicate several times a day and genetic mutations, and thus resistance, can occur with every replication. Patients must take the drugs as prescribed without missing any doses. If a dose is missed, the virus may

develop resistance to those drugs (because it multiplies so quickly and mutations are more likely), reducing the long-term effectiveness of the ARVs in suppressing the viral load. To complicate matters, HIV does not forget. In most cases, resistance persists even if the offending drug is no longer used. Resistance to one drug may also allow the virus to be cross-resistant to another drug. In addition, if these resistant strains of HIV are then transmitted to others, future treatment for those people and all subsequent people who contract that strain of the virus will be more difficult as the virus transmitted will be the same, drug-resistant virus. Accordingly, in Europe and the United States, where some drugs have been used for nearly two decades, HIV has developed a resistance to certain drug combinations.[15] The only effective means of preventing resistance is to maximise the suppression of viral loads. Even at viral loads of $500mm^3$, there is enough viral reproduction for clinically important resistance to develop.[16]

Different lines of ARV drugs

There are multiple "lines" of ART, so that if a patient is resistant to or has an adverse reaction to first line ART, he or she can change drug combinations and take the second line drugs, which include protease inhibitors. If the second line drugs fail, there are third line drugs that can be taken. Currently, first-line drug combinations cost just over 100 USD per patient per annum in India (5000 Rs.),[17] while second-line drugs may cost 1,470 USD (72,000 Rs.).[18] In resource poor countries in particular, the cost and availability of these second and third line drugs is prohibitively high and unreasonable for the vast majority of PLHA.

There is some indication that this may be changing, however, as the Clinton Foundation brokered a deal in 2006 allowing generic drug manufacturers (Cipla, Ranbaxy, Aspen) to produce second line drugs at dramatically lowered prices.[19] The cost of second line treatment in

15 Bosely, Sarah, *Clinton Strikes Deal for Cheaper AIDS Drugs and Fast HIV Tests*, The Guardian, Friday January 13, 2006

16 http://www.cicatelli.org/Expertise/downloadable/FAMHA_winter_04_v3.pdf

17 http://timesofindia.indiatimes.com/Cost_of_HIV_treatment_may_dip/articleshow/2644081.cms

18 http://health.groups.yahoo.com/group/AIDS-INDIA/message/9570

19 Note 15, supra

66 developing countries has now been brought down to Rs. 47,951 per person per year, but in India the cost for the same drugs is Rs. 1,00,000 per person per year.[20] This is due to the fact that at the time of the Clinton Foundation negotiations, the Government of India had no plans to introduce second line treatment to those in need in India, despite the fact that of the seven generic drug manufacturers from whom the Clinton Foundation procures generic drugs, six of them are either Indian-owned or have their headquarters in India.[21]

The provision of ART to a single individual is a complicated process. ARV drugs can result in drug toxicity – this is the term used to describe the dangerously negative side effects of prescribed drugs. In the case of ARV drugs, the potential for drug toxicity is high, and the negative side effects are potentially lethal. Furthermore, patients must often follow specific nutritional guidelines for certain drugs, and medical care providers must check patient progress to see whether the patient is responding to the drug. ARV drugs are too volatile and potentially dangerous to be viewed in isolation. A piecemeal approach is dangerous and potentially counterproductive, complicating the epidemic and unravelling the benefits of providing access to first line drugs. Any belief that mere provision of pills is the solution is simply wrong. Provision of ART is a critical step, but merely the first step of many which cannot be taken without comprehensive planning for the consequences and necessary support.

In resource-poor contexts where medical support and follow-ups may be inadequate and/or difficult to maintain, countries must consider the fact that providing access to antiretroviral drugs may in fact worsen the nature of the epidemic if negligently implemented. If ART programmes are not implemented in conjunction with focus on preventing the transmission of HIV from those undergoing ART and with close monitoring of treatment adherence, the final result of the battles for access to ART may result in an epidemic of wasted, ineffective ART and new strains of resistant HIV that cannot be treated with available drugs. There is some evidence

20 http://www.globalhealth.org/reports/text.php3?id=355

21 http://www.clintonfoundation.org/download/?guid=62e82ddc-98de-102b-be34-001143e0d9b6

from Kenya, for example, which suggests availability of ART without strengthened prevention measures has the effect of "disinhibition," in effect, encouraging higher risk sexual behaviour.[22] Some research has however indicated that PLHA in developing countries actually show increased adherence and responsibility with access to ART. Prevention programmes must be implemented in coordination with any massive ART rollout.

Further, access to ART must mean consistent, efficient access. Symbolic provision of ART in well-publicised roll-outs unaccompanied by steady maintenance is arguably worse than not providing drugs at all. Failed ARV policy can produce a devastating domino effect, causing the drugs to fail in the individual, the virus to develop resistance, and ultimately create new strains of drug-resistant HIV in the population making the epidemic even harder to curb.

22 Note 13, *supra*

CHAPTER 3

HIV/AIDS Trends in India Since 1986

Epidemic Trends in India since 1986

In June 1981, the first reported cases of HIV emerged in the United States, with infections and deaths increasing rapidly thereafter.[23] It was only a matter of time before India would have its first reported case. In 1986, Dr. Suniti Solomon diagnosed India's first cases of HIV among female commercial sex workers (CSW) in Chennai.[24] Within a year of the first diagnosis, approximately 135 cases of HIV had been diagnosed in India, of which 14 individuals' infections had already progressed to AIDS.[25]

As in other areas of the world, the propagation of the infection in India occurred early on among certain high risk groups, notably injectable drug users (IDU), CSW and men who have sex with men (MSM). High risk groups reached greater than 5% HIV prevalence by 1990,[26] with groups such as CSWs in Maharashtra and IDUs in the north-eastern states of Mizoram, Manipur and Nagaland illustrating the menacing potential of HIV to reach pandemic proportions.[27] In Manipur, for example, prevalence of HIV among IDUs increased from 0% to 50% within the six month period of September 1989 to March 1990; quickly spreading

23 AMA, "Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States, 2003," Journal of the American Medical Association, 2003; 289(19):2493-2495

24 Steve Sternberg, "HIV Scares India's Vast Population," USA Today, 2005; Accessed on 12 July 2008, http://www.usatoday.com/news/health/2005-02-23-aids-india_x.htm

25 AVERT, "Overview of HIV and AIDS in India," Accessed on 18 July 2008, http://www.avert.org/aidsindia.htm

26 Rajesh Kumar, "HIV/AIDS Epidemic in India: Trends, Lessons, Challenges & Opportunities." Website of the 16th International AIDS Conference, 2006; Accessed 16 July 2008, http://www.aids2006.org/Web/TUSY0903.ppt: 2

27 Note 3, *supra*

to the general population, as seen by a sero-positive prevalence of 1% amongst expecting mothers by 1991.[28]

In the early nineties, HIV/AIDS cases in India were rapidly increasing. 242 individuals were known to have AIDS in 1992, a number which more than doubled in a year to 522 in 1993. At this stage, the number of Indians living with HIV had gone from thousands to over a million,[29] HIV/AIDS was affecting the general population en masse in high prevalence states,[30] and HIV/AIDS had reached every state and territory in the country.[31]

Although deaths from AIDS in India are difficult to estimate, and little or no data on AIDS-related deaths has been gathered by the Government, it is clear that twelve years into the epidemic, huge numbers of people were dying. According to the 2000 WHO annual report, there were 1,79,365 AIDS deaths in India in 1998, the vast majority of which were people between the ages of 15 and 49.[32] In 2003, however, the Health Minister of India claimed in Parliament, in response to a written question, that only 2,931 people had died of AIDS in the period 2000-2003.[33] This shows both that accurate record keeping has not been maintained, and that the Government of India has based its programmes on figures which appear to show massive under-reporting. It is not difficult to imagine the pressure families can bring to bear for a death actually attributable to AIDS to be recorded as due to some other cause e.g. heart failure, or pneumonia.

In 2000, the profile of new HIV/AIDS cases by transmission was as follows: 74.17% unsafe heterosexual sex; 7.3% injectable drug use; 7.05% unsafe blood transfusion; 0.58% unsafe homosexual sex; and 10.92% other.[34] At the turn of the millennium, HIV/AIDS was clearly no

28 S. Sarkar, N. Das, S. Panda, T.N. Naik, K. Sarkar, B.C. Singh, J.M. Ralte, S.M. Aier, S.P. Tripathy, "Rapid Spread of HIV among Injection Drug Users in North-Eastern States of India," Bulletin on Narcotics, 1993; 45(1):91-105

29 Hinduism Today, "News in Brief," Himalayan Academy, April 1994; Accessed on 14 July 2008, http://www.hinduismtoday.com/archives/1994/4/1994-4-13.shtml

30 Note 3, *supra*

31 Ibid.

32 Note 13, *supra*

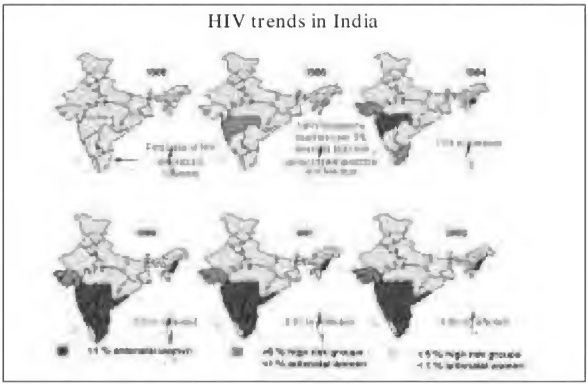
33 http://www.aegis.com/news/afp/2003/AF030817.html

34 Shivananda Khan, "MSM and HIV/AIDS in India," Naz Foundation International, January 2004; Accessed on 20 July 2008, http://www.nfi.net/NFI%20Publications/Essays/2004/MSM,%20HIV%20and%20India.pdf: 1

longer a phenomenon affecting isolated groups of society, rather it was affecting lives in every sector of society, and AIDS was tearing families apart and leaving thousands of children, many of whom were HIV positive themselves, orphaned. A 2002 World Bank estimate suggested that India had the world's largest number of AIDS orphans.[35]

HIV had now become one of the most serious challenges in the country, with epidemics affecting the general population in Maharashtra, Karnataka, Andhra Pradesh, Tamil Nadu, Manipur and Nagaland.[36]

Figure 2: Geographical distribution of HIV, and prevalence by state.[37]



As per NACO figures, the period between 2003 and 2005 saw HIV prevalence amongst high risk groups and the general population (as indicated by antenatal clinic prevalence numbers) begin to level off. In 2004, there were 62,785 AIDS cases reported by NACO.[38]

35 World Bank, "At-A-Glance India: AIDS and Orphans," Accessed 20 July 2008, http://www.parentless.org/Home/LinkClick.aspx?fileticket=R96OqpK0pv0%3D&tabid=58&mid=399: 1

36 Note 26, *supra*

37 Ibid., at slide 2

38 Suniti Solomon, Anirban Chakraborty, Rochelle D'Souza Yepthomi, "A Review of the HIV Epidemic in India," AIDS Education and Prevention, Jun 2004; 16(Supp. A): 158

Table 1: NACO estimates for HIV prevalence among groups at high risk of contracting HIV[39]

HIV prevalence among High Risk Groups				
	2003	2004	2005	2006
FSW	10.33	9.43	8.44	4.90
MSM	8.47	7.47	8.74	6.41
IDU	13.15	11.16	10.16	6.92

Table 2: NACO estimates for HIV prevalence among pregnant mothers attending Antenatal Clinics[40]

HIV prevalence among ANC Clinic Attendeees				
	2003	2004	2005	2006
ANC	0.80	0.95	0.90	0.60

Incomplete and inaccurate data collection by the Government has led to an underestimation of the scale of the epidemic and the needed response

The World Health Organisation estimated that by the end of 2005, of the 22,00,000-76,00,000 PLHA in India 7,85,000 needed ARV treatment but only 24,000 were receiving it, i.e. just over 3% of those in need.[41] Such estimates of HIV infection and need for treatment are only rough estimates because of the dismal job done by the Government in monitoring the epidemic to date.

As of June 2005, NACO claimed there were 1,11,608 AIDS cases in India.[42] Although this may be the number of AIDS cases reported to NACO, it clearly cannot be the true number of AIDS cases in the country. If this were true, India would have by far the lowest proportion of HIV-infected persons developing AIDS in the world. Indeed, the Union of India admitted in its counter-petition in the *Voluntary Health Association of Punjab* case that there were at least 5,10,000 HIV/AIDS cases in India that require treatment, and that that number is increasing each year. Even today in 2008, the Government still does not monitor the

39 NACO, "HIV Fact Sheets: Based on HIV Sentinel Surveillance Data in India 2003-2006," Ministry of Health and Family Welfare, November 2007; Accessed 18 July 2008, http://www.nacoonline.org/upload/NACO%20PDF/HIV_Fact_Sheets_2006.pfd

40 Ibid., at 1

41 http://www.who.int/hiv/HIVCP_IND.pdf

42 http://www.hindu.com/2006/07/30/stories/2006073004851000.htm

number of AIDS deaths per year in the country, although this information is required to accurately understand the scope of the epidemic.

The lack of accurate information gathering by the Government on PLHA up until around 2005 becomes dramatically apparent at the state level. According to NACO, up until mid-2006, Chattisgarh had never had a single AIDS case, and almost all states were clearly underreported – see for example Bihar reporting 155 cases, Orissa 467 and Jammu and Kashmir only two.[43]

The Government of India still does not, however, follow up in a uniform manner with those people who drop out of treatment programmes to find out whether e.g. they have moved away, whether they have died, whether they have developed drug toxicity, whether they found supplies of their prescribed drugs unavailable at their nearest ART centre etc.[44]

Despite an increase in the quantity and quality of data relating to HIV/AIDS epidemiology in India, there was a large shift in the reported statistics in summer 2007, when the Government of India came out with a drastically revised figure for the total number of PLHA in India. Prior to 2007, the estimated number of PLHA in India had been placed at 5.1 million – and this figure was quoted and supported by NACO and the multilateral agencies which had been involved in the surveillance process.[45] Current estimates, announced in summer 2007, now place the figure at around 2.5 million PLHA in India.[46] It is first of all important to recognise that this does not represent a decline in the number of people living with HIV/AIDS in India. It represents merely a change in the way they are counted. These new figures are also supported by the WHO, UNAIDS and the World Bank. Many parts of society are surprised and sceptical about this dramatic shift in the Government's approach to measuring the problem, and the way in which the figures

43 http://www.avert.org/indiaaids.htm

44 This information was provided to HRLN by representatives of the positive networks attending the Access to Treatment Consultations in 2007 and 2008

45 See, for example, http://siteresources.worldbank.org/INTEAPREGTOPHIVAIDS/Resources/UNAIDS_asia_en_pdf.pdf, http://www.unaids.org/unaids_resources/images/ICC_UNAIDSresources/UNAIDS-ICC_Broadcasters_2005.doc

46 UNAIDS & WHO, "2007 Asia AIDS Epidemic Update: Regional Summary," 2007, Accessed 20 July 2008, http://data.unaids.org/pub/Report/2008/jc1527_epibriefs_asia_en.pdf: 5.

have been compiled. If the new figures are correct, agencies involved in monitoring the data up until 2007 had been getting it seriously wrong for a number of years. Human Rights Law Network is deeply sceptical about the downward revision and intends to carefully analyse the data and methodology used to arrive at the reduced figures. PLHA groups reported they had not been involved in the survey, and there were many who questioned whether the review involved sleight of hand. Whatever the truth behind the new numbers, there is still a huge number of PLHA in India – the third largest in the world (behind Nigeria and South Africa), even with the new figures.

Presently, the characteristics of the HIV/AIDS epidemic in India vary considerably by region. In the north eastern states, the epidemic is largely a result of injectable drug use, whereas in the southern and western states, the epidemic is fuelled largely by unprotected heterosexual sex.[47]

HIV Treatment and Policy in India

In the same year HIV was first discovered in India, the U.S. Food and Drug Administration approved the first antiretroviral drug—Zidovudine (AZT)—used for preventing HIV replication.[48] The discovery that AZT – a drug originally meant for cancer treatment – was effective in the reduction of HIV replication in the body, represented hope for a better life for the tens of thousands of HIV positive persons worldwide. That said, with AZT being one of the most expensive drugs ever to hit the market,[49] it also represented the beginning of a struggle that continues today for affordable treatment, as this drug was and remains prohibitively expensive for the vast majority of HIV positive persons in developing countries. In 1986, the Government of India (GOI) responded to the emergence of HIV in India by forming the National AIDS Committee, which was charged with the task of developing a strategy to deal with HIV/AIDS.[50] The committee launched the National AIDS Control

47 http://www.avert.org/aidsindia.htm

48 Michael Shernoff & Raymond A. Smith, "HIV Treatments: A History of Scientific Advance," The Body: the Complete HIV/AIDS Resource, July 2004; Accessed 21 July 2008, http://www.thebody.com/content/art30909.html

49 Catrin Schulte-Hillen, "Study Concerning the Availability and Price of AZT," MSF Report, October 1999; Accessed 21 July 2008, http://www.haiweb.org/campaign/novseminar/schulte_text.html

50 NACO, "About NACO," Ministry of Health and Family Welfare—Government of India, 2007; Accessed on 14 July 2008, http://www.nacoonline.org/About_NACO

Programme (NACP); but with a scope limited to monitoring HIV infection rates among high risk populations in select urban areas.[51] In the early years of the National AIDS Control Programme, no solution to the astronomical price of treatment had been provided for the hundreds of Indians already detected as positive.

The final decade before the turn of the millennium saw certain advances, which created a more encouraging outlook for the future of HIV treatment in India. First, some relief arrived with the advent of Indian generic ARV drugs in 1991. Indian companies began to produce generic versions of AZT, which were available at one quarter of the price of patented AZT.[52] GOI increased its commitment to controlling the epidemic by establishing the National AIDS Control Organisation (NACO) in 1992, which launched the first phase of the new, broader National AIDS Control Programme (NACP-I) later that year.[53] New drugs emerged, leading to therapeutic strategies that combined drugs that would fight different processes of the HIV life-cycle (as explained in Chapter 2), leading to vastly more effective therapy than using a single ARV. By the start of 1997, combination therapy became the standard for HIV treatment, and remains as the standard today.[54] It did not take long for Indian generic manufacturers to produce cheaper versions of such drugs.

While the progress of the 1990s seemed promising, one stinging fact remained: the overwhelming majority of HIV positive individuals living India were not receiving treatment of any kind whatsoever. A 2002 report[55] suggested that, of the 5,55,000 people living with AIDS in India; only 2.2% were receiving antiretroviral treatment.[56] Moreover, more than half of those receiving treatment were not adhering to their treatment regimen by the end of the first year due to the high costs of the drugs and tests.[57] At the time of the report, the average expenditure for

51 World Bank, "HIV/AIDS—India," 2008; Accessed 17 July 2008, http://go.worldbank.org/FKLVQCCF40

52 Carin Håkansta, "The Battle on Patents and AIDS Treatments," Biotechnology and Development Monitor, 1998; 34:16-19

53 Note 26, *supra*

54 Note 24, *supra*

55 Hira, Subhash K. (2002) "Pattern of Resistance to ARV Drugs in Mumbai" Paper presented at The Second International Conference on HIV/AIDS and Substance Abuse, 1-3 December 2002, Mumbai

56 Note 13, *supra*, at 25

57 Note 13, *supra*, at 22

people on ART was Rs.2,498 per month for drugs, Rs.5,585 for initial tests and Rs.5,155 every six months for monitoring tests.[58] Considering the average income in India in 2002 was Rs.1,686/month (based on an average income of $470/yr[59] and an average exchange rate of 1 USD = 43.055 INR[60]), and more than 86% of the total population was living on less than $2/day (or Rs.86/day),[61] it is clear that a majority of HIV positive individuals simply could not afford treatment. Whilst important achievements in capacity building of management and technical aspects of the National AIDS Control Programme were attained, even in 2002, treatment remained outside the scope of the programme.[62]

In 1999, NACO came out with its programme for National AIDS Control Programme, Phase II (NACP-II). The stated objectives of NACP-II appeared to demonstrate the Government's recognition of the importance of treatment for HIV and commitment to providing treatment and prophylaxis for opportunistic infections (OIs), and hospice care for terminally ill AIDS patients.[63] Despite these words, public spending on therapy for HIV represented an estimated 5% of the total amount of money spent in India on HIV treatment in 2002 (the Government of India financed and provided somewhere between 10 and 20% of the general health care spending in the country in the same period).[64]

These numbers mean that the reality for most positive individuals in India is that there is no treatment available, as was the case for 37 year-old Sharma's late husband. Sharma, a school teacher from Bhopal, learned that she was HIV positive when her husband, who had become positive following a blood transfusion, developed HIV/AIDS. Sharma was lucky and was able to receive treatment by moving to Chennai, funding it with her teaching salary. Her husband's case, however, represents the majority – he died in March of 2004 without having received any treatment because they could not afford it at the time. Sharma explained

58 Note 13, *supra*, at 30

59 World Bank, "At-A-Glance India," 2004; Accessed 20 July 2008 http://siteresources.worldbank.org/INTINDIA/Resources/AnnexureB.pdf

60 CIA Factbook 2002—India, Accessed 14 July 2008, http://www.umsl.edu/services/govdocs/wofact2002/geos/in.html#Econ

61 Note 50, *supra*

62 Note 3, *supra*

63 M Prasanna Kumar, "The National AIDS Control Program (1,2, and 3)," Infochange, 2008; Accessed 25 July 2008, http://infochangeindia.org/hivonline/response_1.plp

64 Note 13, *supra*, at 54

that her husband had received a death sentence from their physician:

"the doctors in Bhopal told us they didn't have any treatment for HIV...It's only available in foreign countries."[65]

As highlighted in Chapter 1, the Government of India has since made a number of promises relating to care and treatment for PLHA which it has failed to keep. As a result of pressure brought to bear through the *Voluntary Health Association of Punjab* case, a national roll-out of first line ARV drugs was announced by the then Health Minister (the timing of this coupled with the availability of good quality generic drugs available from Indian manufacturers). Initially, the government said its target was to bring 1,00,000 people onto ART by December 2005. By February 2006 however, only 26,000 were receiving treatment from NACO's roll out[66] and one year later after the initial target date, by December 2006, only 56,000 people were receiving ART[67] and only 1860 children across the whole country.[68] As will be seen in Chapter 5, reports from the positive networks during this roll out tell of unavailability of medicines, acute lack of trained and sensitive medical staff at any of the ART centres, disruptions in supply and a lack of publicity regarding the roll out. In Sangli, patients were asked to sign an informed consent form, agreeing to pay for tests if needed and to buy drugs from the market if the supply is suddenly stopped.[69]

By February 2007, the government had just under 60,000 people receiving ART[70]- still 40,000 short of its initial target to be met by the end of 2005. A look at the NACO website shows that there was no shortage of funds during this period, and the incredibly slow roll out of ART centres and ART for those in need is difficult to comprehend, particularly in light of the Government's admission in its pleadings before the Supreme Court that there were 5,10,000 PLHA in need of treatment in India.

65 Note 3, *supra*

66 http://www.nacoonline.org/upload/naco%2520newsletters/Nov-Feb-1.pdf

67 http://infochangeindia.org/hivonline/response_1.php

68 http://www.nacoonline.org/upload/naco%20newsletters/NACO%20Newsletter%20-%20Vol.%20III%20Issue%20%201%20-%20%20Jan.-Mar.%202007.pdf

69 http://www.icaap8.lk/programme_at_a_glance/track_c/downloads_ppt (reported by Ms Meena Seshu of Sangram, a Sangli-based NGO)

70 http://www.nacoonline.org/upload/naco%20newsletters/NACO%20Newsletter%20-%20Vol.%20III%20Issue%20%201%20-%20%20Jan.-Mar.%202007.pdf, at page 19

By the end of August 2007, NACO had finally managed to achieve its target set in 2004 of getting 1 lakh people onto ART.[71] As of July 2008, NACO's ART centres are treating 1,50,961 people – far short of the number actually in need.

The Government will have been aware of the fact in 2004, when it started slowly making first line ART available to PLHA, that drug resistance was likely to develop in a significant portion of those starting treatment and that second line treatment would be required for those people, as well as others who had initial resistance to first line ART. Despite this, and despite ample evidence from countries where first line programmes had begun much earlier, the Government, had no plans to introduce second line treatment whatsoever, until very recently. Even now, as will be seen below, the roll out for second line treatment is even slower than the roll out for first line treatment was.

In January 2008, NACO began making second line treatment available as part of a pilot programme at two hospitals in India – one in Tambaram (Chennai) and one in Mumbai. People outside of these places will not receive ART until there is a full roll out.[72]

NACO has claimed a pilot programme is necessary to properly evaluate areas such as drug adherence, drug resistance and toxicity and performance of the drugs.[73] None of the drugs being provided through the pilot programme is new, they have been used for years in other countries and there is therefore a great deal of evidence available on these issues in relation to these particular drugs.

The government has said it will expand the second line treatment programme "in a phased manner", although the time line for this expansion is conspicuously vague. By the end of 2008, there should be ten centres offering second line treatment, but as this excerpt from a report in The Statesman, an Imphal-based newspaper shows, there are serious problems with the roll out:

"For hundreds of people living with HIV in Manipur who have developed resistance to the first line Anti-Retroviral Therapy (ART)

71 http://www.nacoonline.org/upload/naco%20newsletters/Vol.III%20Issue%203%20-%20Jul.-sep.%202007.pdf

72 http://community.worldaidscampaign.net/showthread.php?t=287

73 http://health.groups.yahoo.com/group/AIDS-INDIA/message/9451

~ the only known treatment that can suppress HIV, news of free second line treatment came as manna from heaven. But the euphoria faded and trauma took over as the state agency set up to deliver the free therapy failed to do so even though the first of the drugs consignments has already arrived in Imphal.

"While the Manipur AIDS Control Society, the nodal agency, scrambles to roll out the therapy, calling a meeting of its Nodal officials on the 24th of this month, the RIMS ART centre, one of the 10 designated across India to administer the second line treatment is yet to be fully conversant with the drug regime. Except for the RIMS Nodal Officer of the ART centre, no one even knew of the arrival of the drugs.

"The drugs, part of the consignment given by the Clinton Foundation through NACO following its request was reallocated from the Tambram ART centre specifically for RIMS.

"According to reports NACO has set November as the deadline for rolling out the drugs.

"But from the way things are turning out it is unlikely that the drugs will be delivered. Inside information say a four-member committee to look into who deserves to be given second line treatment is yet to be formed. More importantly there seems to be not enough trained hands to administer the drug regime. Authorities at the RIMS ART centre are citing technical problems, saying that viral load test of the patients need to be taken before the administration and that it cannot be done in Manipur.

"They also say that it cannot give out the drugs given the lack of directive on the viral load testing from either the Macs or Naco. Sources however say Naco has made arrangement for testing of viral loads for blood samples from Manipur at Delhi centre to which it is connected by daily flight.

"The Clinton Foundation, it is learnt is also supporting the viral load testing."[74]

The government is also currently refusing to supply second line treatment to people who have been obtaining either first or second line treatment

74 http://www.thestatesman.net/page.arcview.php?clid=2&id=254231&usrsess=1

from the private sector.[75] This is grossly unfair and is likely to lead to more people ceasing ART as they become unable to afford it from the private sector. It will also lead to greater poverty for more families, as they choose between buying drugs and food.

At the time of going to print, second line treatment had been announced for hospitals in Delhi, Kolkata, Imphal, Ahmedabad, Hyderabad, Karnataka, Chandigarh and Uttar Pradesh.

Funding and Mainstreaming

The Government must better incorporate its HIV/AIDS treatment programme into the general health care system. For example, tuberculosis treatment centres and ART centres are often located far from each other, and there is a chronic lack of communication between the two. Tuberculosis is one of the most common opportunistic infections associated with HIV, and treatment should be conveniently available for PLHA. Similarly, those with tuberculosis should be able to easily get themselves tested for HIV in appropriate facilities. It is essential, however, that these centres not be in the same actual space, as is the case in a hospital in Tamil Nadu, as PLHA are highly susceptible to tuberculosis, which is very contagious. Limited attempts have been made by the Government to partner its HIV/AIDS and tuberculosis programmes, but the lack of incorporation nationally, despite years of recognition of the relationship between the two health issues, signifies an overall inattentiveness to the HIV/AIDS epidemic.

As ART centres are often located far from those who need treatment, adherence to ARV drugs drops for these individuals, creating a risk to their health and the general population as the likelihood of resistance increases. To combat this problem, comprehensive treatment, including availability of ARV drugs, needs to be available at a district level. NACO has already noted that this must be the ultimate goal of the Government programme. (Draft NACO Guidelines detail this goal; the Draft NACO Guidelines also envision a programme in which each patient has access to a primary health care provider in their community whom could help administer the drugs, and then visit a district hospital once every six months for tests.) Most recently, the Government has promised that 650

75 Note 70, *supra*

link ART centres will be functional by 2010.[76] These link ART centres, provided they are adequately staffed and resourced, are a useful way of ensuring people living far from urban centres and ART centres can obtain reliable sources of ARV drugs. They are also playing a crucial role in monitoring drug adherence. It remains to be seen whether the Government will be able to fulfil its promise of 650 link ART centres over the next year and a half.

Lack of Public-Private Partnership in HIV/AIDS Treatment Programme

It is startling that there are treatment problems in the private and non-profit sector as well, and that the many well-trained non-profit and private HIV/AIDS doctors in India have not yet been brought into the Government's HIV/AIDS programme. Many of the country's best and most experienced HIV/AIDS doctors are in the non-profit and private sector and more are being trained every day. The Government must create a voluntary accrediting programme (through onsite inspection) to begin to be able to use these doctors as an extension of the Government programme. To prevent corruption, a monitoring process could be easily developed to ensure these doctors do not charge patients for drugs they are receiving from the Government for free.

The Clinton Foundation pledged in 2005 to train 1,50,000 doctors in the private sector in India in HIV/AIDS treatment and care.[77] While the Government suffers from a lack of trained AIDS doctors in the public sector, some of the world's best AIDS doctors are forced to turn away patients because they cannot afford drugs. This is an intolerable and perverse situation.

Some countries, such as Brazil, already provide free Government ARV therapy through the private and non-profit sector as well as a reasonable set fee for these doctors' services. There are even companies that will assist Governments in scaling up such public-private partnerships if the help is needed. The incorporation of accredited doctors in the non-profit

76 This is contained in the Government's proposed 19-point directions to the Supreme Court in *Voluntary Health Association of Punjab* which can be read here: http://groups.google.co.in/group/AIDS-Beyond-Borders/browse_thread/thread/c011fea166f7bdcb?pli=1

77 http://www.clintonfoundation.org/news/news-media/052605-nr-cf-hs-ai-ind-pr-plan-to-train-150,000-doctors-in-india-in-aids-care-and-treatment

and private sector would dramatically and quickly ramp up the availability of HIV/AIDS treatment in all the states by allowing for treatment options wherever there were qualified and willing doctors available. Many rural areas that could not hope for a treatment programme for years, if ever, under the Government's current policy could have treatment begin almost immediately if there was an accredited doctor available.

Furthermore, by providing free ARV drugs to any accredited doctor in the non-profit or private sector, the Government would greatly reduce the chances of any potential corruption involved in trying to sell drugs from the public sector to the private.

Finally, by giving free HIV/AIDS drugs to accredited doctors in the non-profit and private sectors, the Government can better regulate the private and non-profit doctors who have given incorrect care in the past. A public-private partnership programme gives an incentive to private and non-profit doctors to be well-trained. Such a public-private partnership can also be extended to monitoring and counselling services as well as for HIV testing.

India's private-public partnerships in fighting tuberculosis can serve as a model for such an HIV/AIDS programme. As of March 2004, there were 550 NGOs and more than 2,000 private practitioners involved in the delivery of the Government's tuberculosis programme.[78]

NACO has commented on the usefulness of such public-private partnerships:

> *"Engaging the private sector providers to scale up access to ARV treatment can be helpful means of achieving goals of ART programme in expanding the coverage; ensuring the quality and safety of ARV treatment; and achieving service integration with other prevention, care and support interventions, as well as public health programmes such as STI and tuberculosis programme." (Draft NACO Guidelines)*

What is needed now is the rapid implementation of such a programme to quickly bring access to free ARV drugs through well-trained doctors to the thousands in need.

78 http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/SOUTHASIAEXT/0,,contentMDK:21887522~pagePK:146736~piPK:146830~theSitePK:223547,00.html

The Government has failed to fully utilise the international funding available for HIV/AIDS treatment, and has grossly under-funded its HIV/AIDS treatment and prevention efforts

In 2004, India was spending approximately 29 cents per capita on HIV/AIDS-related programmes. In contrast Thailand was spending 55 cents, Uganda $1.85, and Cambodia $5.70.[79] The majority of the money India spends on its fight against HIV/AIDS comes from foreign sources.[80]

It was reported by human rights groups that, in 2004, the Global Fund against AIDS, Tuberculosis, and Malaria (GFATM) approved a grant for $122 million over four years to fund AIDS treatment efforts in India, but that through incredible negligence, this money was left untapped for over a year.[81] Millions of dollars that could save tens of thousands of lives were left to languish in bureaucratic hold-ups.

The Government also needs to commit major financial resources to provide treatment for those with HIV/AIDS so that foreign funding provides a supplement and not a basis for the nation's HIV/AIDS programmes. India's epidemic has gathered the concern of the world, which is willing to help India in its fight. However, the Indian Government has not prioritised this struggle. Treatment for HIV/AIDS is a matter vital to the future of the country and, although all reasonable foreign funding sources should be exploited in this effort, India must lead in financing its own treatment efforts.

Discrimination

HIV has been met by Indian society with relentless discrimination that severely impairs prevention and treatment efforts. HIV/AIDS-related stigma and discrimination add another layer to the epidemic, as well as exacerbating pre-existing stigma and discrimination related to gender, sexuality, and poverty.[82] The first assumption one will make of a positive person is often that they are a member of one of the "high risk groups",

79 http://www.twq.com/04autumn/docs/04autumn_mitra.pdf

80 http://www.nacoonline.org/About_NACO/Funds_and_Expenditures/

81 Richard Stern, "*Indian Government Bureaucracies Kill Off People Living with AIDS*" available at http://health.groups.yahoo.com/group/AIDS-INDIA/message/4444

82 Richard Parker, Peter Aggleton, Kathy Attawell, Julie Pulerwitz, Lisanne Brown, "HIV/AIDS-related Stigma and Discrimination: A Conceptual Framework and an Agenda for Action," Horizons Program/USAID, May 2002; Accessed 22 July 2008, http://www.popcouncil.org/pdfs/horizons/sdcneptlfrmwrk.pdf: 1.

since the widespread perception is that HIV is only found among MSM, IDU and CSW. Men may avoid revealing their status for fear of being labelled homosexual, and women may fear revealing their status for fear of being labelled "promiscuous" or as a sex worker.[83]

Women are especially vulnerable to discrimination in India, as there is a commonly held belief that they are the vector of HIV.[84] In fact, an Indian study of people who disclosed their HIV positive status to their families, revealed that men more often received care and support, and that women more often were targets of discrimination, including denial of shelter, denial of a share in household property, denial of treatment, and being blamed for the positive status of their husbands.[85]

Judgment and blame are inherent in such beliefs. It is not uncommon for positive persons to be perceived as being punished for immoral behaviour, or being responsible for contracting the virus.[86] These ideas pose one of the most serious impediments to effectively combating HIV/AIDS in India. The words of the late Jonathan Mann, director of the WHO Global Programme on AIDS, summarise this: "[stigma and discrimination are] as central to the global AIDS challenge as the disease itself."[87]

Women are increasingly affected by the HIV/AIDS epidemic in India. Women face a number of particular vulnerabilities. They are, for example, physiologically more vulnerable to transmission of the virus during vaginal sex. They are often unable to demand safe sex practices from their husbands. In a situation where both husband and wife are positive, the wife is often tested positive first, as she accesses ante-natal services. If the wife tests positive and the husband is persuaded to be tested, there is an apparent, though usually false, causal link between the wife's and the husband's positive status.

Institutional discrimination is among the most serious forms of discrimination that cause people to avoid revealing their status, avoid

83 Ibid., at 4

84 Shalini Bharat, Peter Aggleton, Paul Tyrer, "India: HIV and AIDS-Related Discrimination, Stigma and Denial," UNAIDS/01.46E, August 2001; Accessed 13 July 2008, http://data.unaids.org/Publications/IRC-pub02/JC587-India_en.pdf: 9

85 Ibid.

86 AVERT, "Stigma, Discrimination and Attitudes to HIV & AIDS," Accessed on 22 July 2008, http://www.avert.org/aidsstigma.htm

87 Note 13, *supra*, at 1

seeking treatment for fear of breach of confidentiality and avoid getting tested. In some cases, positive people have been denied treatment due to medical discrimination. Instances of discrimination in employment are common in India, with cases of job loss, isolation and denial of employment being reported.[88] Likewise, positive children often face discrimination in schools, with instances of segregation, breach of confidentiality, and children being thrown out of school based on their or their parents' actual or perceived status.[89]

Arguably the most dangerous form of discrimination, and most detrimental to the furtherance of HIV treatment in India, is medical discrimination. Although it has been more than 20 years since the diagnosis of the first cases of HIV in the country, numerous cases of discrimination in medical settings continue to be reported. Moreover, discrimination has been seen in the medical context worldwide, with the most common complaints including refusal of treatment, neglect of patients, testing without consent and breaches of confidentiality.[90] These traumatic experiences with the health care system are a source of fear, anxiety and cause of the denial of one's HIV positive status.[91] Such anxieties are understandable when one reads about cases such as that of a 26-year-old man who died of renal failure at a Delhi hospital, when denied treatment based on his HIV status. One of the hospital's doctors admits "His case sheet says that he was refused treatment because he was HIV positive…He died within two hours."[92] Similar inhumanities have been committed by police dealing with positive people, judges and lawyers with positive complainants, officials holding public office who have ignored the needs of their positive constituents, and the list goes on.[93]

High risk groups face special problems vis-à-vis discrimination, thus providing adequate treatment to these groups is especially challenging.

88 Note 82, *supra*, at 10

89 Ibid.

90 Note 48, *supra*, at 10

91 Ibid.

92 Reuters, "Indian AIDS Patient Dies as Doctors Deny Treatment," 16 December 2006, Accessed 15 July 2008, http://www.alertnet.org/thenews/newsdesk/DEL79394.htm

93 See, for example, the circumstances at issue in *X v Gov't of NCT Delhi and Ors.*, before the Court of the Metropolitan Magistrate, Karkadooma, New Delhi, in which the police refused to file an FIR on behalf of three PLHA who had been cheated by a quack advertising drugs which could cure HIV/AIDS, a charge which the quack had admitted

Common to the three groups at the highest risk of contracting and spreading HIV (CSW, MSM and IDU) is that the criminality of their behaviour drives their practices underground. As such, these communities are extremely difficult to reach out to with prevention and treatment programmes. The overall effect of this extends beyond these communities, as prevalence of HIV in the general public is ultimately a function of prevalence among high risk groups. In fact, two of the most crucial factors determining the rate of growth of HIV infections in India are the population of sex workers and the rate of condom use with their clients.[94] Moreover, injectable drug users are a major driver of the epidemic, especially in the north-east, where their intersection with sex workers has increased the rapidity with which the infection is growing.[95]

94 Mariam Claeson and Ashok Alexander, "Tackling HIV in India: Evidence-Based Priority Setting and Programming," Health Affairs, 2008; 27(4): 1091-1102

95 Ibid.

CHAPTER 4

Universal Access to HIV/AIDS Treatment: A Fundamental Right

The Government of India had a 'prevention only' approach to HIV/AIDS entirely ignoring the treatment component until April 2004. A prevention-only approach to HIV ignores the right to health of those who need care, violates their dignity, devalues their lives, and fuels stigma and discrimination against their HIV positive status.

As set out below, international treaties strongly articulate the universal rights to life and health, while foreign jurisprudence shows that these rights have been interpreted to mean Governments must provide comprehensive HIV/AIDS treatment. The right to HIV/AIDS treatment is founded on the right to life in Article 21 of the Indian Constitution, and is supported by case law and international law. International treaties make clear the connection between the right to life and the right health. These rights demand the Government provide HIV/AIDS treatment for those in need when it is within the Government's ability to do so. In many countries, the judicial system has enforced these rights to ensure that HIV/AIDS treatment is available to all those individuals in need.

International Treaties

Article 25(1) of the Universal Declaration of Human Rights (UDHR) articulates a basic right to health:

> *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."*

Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR) reaffirms and builds upon the right to health found in the UDHR by recognising,

> *"The right of everyone to the enjoyment of the highest attainable standard of physical and mental health."*

It further requires that:

> *"steps to be taken by the States Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for ... (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness."*

The right to health in the ICESCR is subject to the principle of progressive realisation found in Article 2.1.

Article 6.1 of the Convention on the Rights of the Child states:

> *"States Parties recognise that every child has the inherent right to life."*

Article 6.2 states:

> *"States Parties shall ensure to the maximum extent possible the survival and development of the child."*

The Committee on the Rights of the Child has spoken on the issue of HIV/AIDS in particular as it affects children being orphaned and, therefore, affects their health and development and even their very survival.

International Jurisprudence

Courts around the world have used the right to life and health, and principles of non-discrimination found in their constitutions and international law to ensure their respective Governments provide HIV/AIDS treatment to those in need.

In 1992, in *Diego Serna Gómez v. Hospital Universitario del Valle,*[96] the Columbian Constitutional Court found that the Government's social

96 Decision T-505 of 1992, Eduardo Cifuentes Mutild noz, J. (unanimous)

security scheme must provide HIV/AIDS treatment to those in need (at this time ARVs were not yet commonly used to treat HIV/AIDS). It based its decision not only on principles of human dignity, but also of non-discrimination, as not treating HIV/AIDS added to the stigma of those living with the disease and constituted economic discrimination because only those who could afford to, received treatment.

In 1995, in *XXX v. Instituto de Seguros Sociales (ISS),*[97] the Columbian Constitutional Court extended the scope of its judgment in *Gómez* to state that the Government's social security scheme must also include the provision of ARVs to those who medically needed them.

In 1997, in *William García Álvarez v. Caja Costarricense de Seguro Social*[98] the Costa Rican Supreme Court ruled that ARVs must be provided through the Government's social security scheme. The court based its decision on the importance of the rights to life and health in a modern society:

> *"If the right to life is especially protected in each modern State and with it the right to health, any economic criteria that pretends to deny the exercise of those rights, has to be of second importance [...] without the right to life, all the remaining rights would be useless."*

This decision was handed down in 1997 when ARVs were considerably more expensive and less effective than today. Nonetheless, the court found sound economic policy on which to base its order to the Government to provide ARVs:

> *"...if what is necessary is to put the problem in the cold financial dimension, the Court believes that it would not be less on target to ask ourselves about the many millions of colons [Costa Rican currency] that are lost by the fact that the sick cannot have the possibility of reincorporating themselves into the labor force and producing their part, however small it may be, of the national riches. If we enter this extreme, and all those that are associated with it, it is reasonable to postulate that the country loses more by direct and indirect costs of the state from the incapacity of one lying prostrate because of a sickness, than what in another manner would be invested giving*

97 Sentencia T-271/95, Exp. 62714, of Seventh Court of Revision of the Constitutional Court (June 23, 1995)

98 *Mr. William Garcia Alvarez v. Caja Costarricense de Seguro Social*, Constitutional court of Costa Rica, File 5778-V-97, 23 September 1997

him the treatment that would permit him to return to a productive life. Of course, the intangible, social, and moral benefits are – unquestionably – much greater."

In *Cruz del Valle Bermúdez et al. v. Ministerio de Salud y Acción Social,*[99] an action was filed by a group of Venezuelan NGOs demanding ARV treatment be provided by the Government's social security scheme under the right to health in the Venezuelan Constitution, and under international treaties such as the ICESCR. Citing the right to health, the Court held in 1999 that the Government must provide ARV therapy under its social security scheme. The Venezuelan Supreme Court ordered the Ministry of Health to request the necessary funds from the President for prevention and control of HIV/AIDS, and also ordered the Ministry of Health to provide ART and associated medicines to those in need in Venezuela. The Supreme Court made it clear it expected all Governmental authorities to comply with the spirit and letter of its Order in this case.

In 2000, the Argentinean Supreme Court in *Asociación Benghalensis et al. vs. Ministerio de Salud y Acción Social*[100] held that the Ministry of Health was not fulfilling its duty to provide ARVs through public hospitals. For the basis of its decision, the Court cited the right to life and health found in the Argentinean Constitution. A great number of people benefited almost immediately from this decision.

In 2001, the Supreme Court of El Salvador in *Jorge Odir Miranda Cortez v. Director of the Salvadoran Institute of Social Security*[101] held that the El Savadorian Government must provide ARV therapy and other medications that prevent the death and improve the quality of life of persons living with HIV/AIDS. The court found that:

"if one person who should be attended in a specific manner does not receive the corresponding attention, so that he is condemned to an undignified life or even to death, this would frontally attack the right to health and even more, to life, protected by the Constitution [...] A person's right to enjoy good health through the effective and prompt intervention of the State's assistance translates at the end of the day into an attempt to extend life, but with dignity. Dignity is a principle that informs the entire juridical system, and life is a right that makes possible the existence of the other rights."

99 Supreme Court, expediente no. 15789 (July 15, 1999; Venezuela)

100 Supreme Court of Justice of Argentina, Fallos 323:1339, 1 June 2000

101 Constitutional Court of El Salvador, File n°348-99, 4 April 2001

Citing the Costa Rican Supreme Court's decision in *Álvarez*, the El Salvadorian Supreme Court concurred that providing ARVs to its population would save the Government money by keeping its citizens out of hospitals and in the workforce.

Also in 2001, in *Glenda Lopez et al. v. Instituto Venezolano de Los Seguros Sociales,*[102] a follow-up case to *Cruz del Valle Bermúdez*, the Venezuelan Supreme Court reaffirmed its orders that ARV treatment must be made available to all who needed it under the social security scheme and demanded compliance with these orders.

In 2002, the South African Constitutional Court held in *Treatment Action Campaign v. Minister of Health and Others,*[103] that the Government must provide nevirapine in public hospitals to help prevent mother-to-child transmission of HIV. In doing so the court cited not only a right to health found in the South African Constitution, but that the use of nevirapine during an HIV positive pregnancy was part of a minimum core of rights to which everyone is entitled. The South African Court found that the UN Committee on Economic, Social, and Cultural Rights had developed the concept of this minimum core and the South African Constitutional Court based its decision on a series of rights found in the South African Constitution. The Court stated:

> *"This minimum core might not be easy to define, but includes at least the minimum decencies of life consistent with human dignity. No one should be condemned to a life below the basic level of dignified human existence."*

This case, its context and impact is discussed in greater detail in Chapter 7 of this book.

Indian Law on Access to Treatment

The international community has endorsed the importance of human rights, but the guarantee of rights in the health sector remains the principal responsibility of States, and they must convert the rights into a cognizable reality. The Indian legal system's ability to guarantee the right to health is entrenched in the Indian Constitution and the creative interpretation of the constitutional provisions by the Supreme Court of India.

102 Supreme Court, expediente no. 00-1343 (April 6, 2001; Venezuela)
103 Constitutional Court, South Africa,2002

Article 21 provides:

> *"No person shall be deprived of his life or personal liberty except according to procedure established by law."*[104]

The Indian Supreme Court has recognised in its jurisprudence (set out in detail below) that the right to life is meaningless unless accompanied by the guarantee of certain social rights, which make possible the chance to live life with dignity.

Article 47, a Directive Principle,[105] directs the Government to improve public health, stating *"The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties."* Although Article 47 is not justiciable per se, together with Articled 21, it forms a constitutional parallel to international human rights standards enumerated in the ICESCR, ICCPR and other international instruments to which India is a signatory, or which it has formally ratified.

Indian Supreme Court Decisions Interpreting the Right to Life

Beginning in 1981, in *Frances Mullin v. Union Territory of Delhi*, the Indian Supreme Court has interpreted the right to life expansively to include *"the right to live with human dignity and all that goes along with it, namely, the bare necessities of life such as adequate nutrition, clothing and shelter."*[106] Central to jurisprudence on the right to life, as confirmed by later cases, is human dignity, a concept derived from the Directive Principles and generally indicating the provision of basic needs to provide an enabling environment to make *"life meaningful and worth living."* The Supreme Court has explicitly held this right to mean more than *"mere survival or animal existence."*[107] Building upon its own jurisprudence, the Court took the next logical step and included the right to health as a necessary component of the right to life and the right to live

104 Article 21: Constitution of India, 1950

105 Directive Principles of State Policy are set out in the India Constitution, and form guidelines to the current government for the framing of legislation. They are not enforceable by the Courts

106 (1981) 2 S.C.R. at 529

107 *Dr. Ashok v. Union of India,* (1997) 5 SCC 10; Bandhua Mukti Morcha, A.I.R. 1984 S.C 802, 811

with human dignity. It did so by deftly integrating the non-justiciable Directive Principles into the justiciable Fundamental Rights, explicitly holding that "[t]he right to health…is an integral facet of [a] meaningful right to life."

Since *Mullin*, the non-justiciability of the State health policy and State obligations to ensure health for its citizens has been replaced by a developing jurisprudence that imposes obligations on the State to provide enabling social conditions for the development of health, life, and ultimately human dignity. The elevation of the right to health serves as an indication that the law recognises a rights violation in the non-provision of sufficient access to health care services, as well as providing a powerful vehicle for litigation seeking the protection of the health of PLHAs.

With the recognition that the fundamental right to life in Article 21 of the Constitution emphasises the value of human dignity, the Supreme Court began to address the importance of health as a fundamental right for Indian citizens. In addition to Article 47, the right to health also has its genesis in Articles 38,[108] 39(e),[109] 41[110] and 48A[111] of the Directive Principles. In a series of cases, the Supreme Court has addressed the issue of health care as a fundamental right and has imposed an obligation upon the state not only to provide emergency medical care but also to

108 State to secure a social order for the promotion of welfare of the people.- (1) The State shall strive to promote the welfare of the people by securing and protecting as effectively as it may a social order in which justice, social, economic and political, shall inform all the institutions of the national life. (2) The state shall, in particular, strive to minimise the inequalities in income, and endeavour to eliminate inequalities in status, facilities and opportunities, not only amongst individuals but also amongst groups of people residing in different areas or engaged in different vocations

109 Certain principles of policy to be followed by the State:- The State shall, in particular, direct its policy towards securing. (e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter vocations unsuited to their age or strength;

110 Right to work, to education and to public assistance in certain cases.- The state shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want

111 Protection and improvement of environment and safeguarding of forests and wild life - The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country

take all steps to create conditions necessary for good health, including facilities for basic curative and preventive health service. The Court has required States to provide citizens with basic health services and social conditions essential for the enjoyment of health.

In *Bandhua Mukti Morcha v. Union of India,*[112] the Supreme Court addressed the types of social conditions necessary for the enjoyment of health. The issue presented in the case was whether the workers at stone quarries were deprived of their right to life because of inhumane living and working conditions. The Supreme Court stated that the right to live with human dignity includes protection of the health of individuals. It also held that State actors must provide the basic conditions necessary for the enjoyment of health in order to guarantee the right to live with human dignity. The Supreme Court found that the State was required to provide workers with clean drinking water, sanitation facilities, and medical facilities to protect their health and that this obligation was founded on the workers' right to life under Article 21 of the Constitution.

In *Consumer Education and Research Centres & Others. v. Union of India,*[113] the Supreme Court held that the right to health and medical aid to protect health is a fundamental right and that health implies more than an absence of sickness. The Supreme Court in another case reiterated that that the right to health is integral to the right to life and that the Government has a constitutional obligation to provide healthcare facilities.[114]

In a further case, the Supreme Court held that the right to life embodied by Article 21 cast a responsibility on the State to guarantee a healthy life to its citizens. This duty was reaffirmed by Article 47 and was one the most essential obligations of the state.[115] The apex Court has also recognised that medical care and health facilities not only protect against sickness, but also ensure stable manpower for economic development, and that the maintenance of health is an imperative constitutional goal.[116]

In *Dr. Ashok v. Union of India,*[117] the Court held that the right to life under Article 21 of the Constitution meant more than just mere existence

112 A.I.R. 1984 S.C. 802
113 (1995) 3 SCC 42
114 *State of Punjab and Others v. Mohinder Singh Chawala.* (1997) 2 SCC 83
115 *State of Punjab & Others v. Ram Lubhaya Bagga & Others* (1998) 4 SCC 11
116 *C.E.S.C. Limited and Othrs. v. Subhash Chandra Bose and Others.* (1992) 1 SCC 441
117 (1997) 5 SCC 10

or survival. On the contrary, it included all that gave meaning to man's life, from his heritage to his health, and protected the same. The Court thus expanded the interpretation of the term "life" used in Article 21. By doing so, it brought the prevention of injuries to a citizen's health because of harmful drugs or other substances as well as due to pollution, within the meaning of right to life.

The Supreme Court laid down that the preservation of life was a necessary component of the right to life, as enshrined in Article 21 of the Constitution of India.

In *Paschim Banga Khet Mazdoor Samity & Others v. State of West Bengal & Another*,[118] the Supreme Court held that the primary function of the State was to secure the welfare of its people. Providing adequate medical facilities for them was part of this obligation. The Court, in holding that there had been a violation of the right to life under Article 21 and awarding compensation, stated that the right to emergency medical care formed a core component of the right to health, which in turn was recognised as forming an integral part of the right to life. It did this by re-conceptualising the right to life as imposing a positive obligation on the State to safeguard the life of every person stating that "*preservation of human life was of utmost importance*" and that "*The Constitution envisages the establishment of a welfare State...Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in this respect and discharges this obligation by running hospitals and health centres.*"

Practical Arguments in Favour of Universal Access as a Right

The introduction of national ARV treatment corresponds to a decrease in the rate of new HIV infections

A recent study in Taiwan showed that providing HAART to all HIV positive citizens corresponded with a 53% decrease in the rate of new HIV infections.[119]

In the early 1990s, Brazil initiated the first free ARV programme in the developing world. Today the programme provides free ARV drugs and treatment for opportunistic infection to almost everyone who needs it in

118 Writ Petition. (Civil) No. 796 of 1992

119 "*Decreased HIV Transmission after a Policy of Providing Free Access to Highly Active Antiretroviral Therapy in Taiwan*" by Chi-Tai Fang and others published September 2004

the country (about 130,000 people). In 1992, the World Bank estimated that by 2002, Brazil's prevalence rate would be 1.2% in 2000. Brazil's aggressive treatment programme meant however that the prevalence rate in 2000 was actually 0.6%.[120]

Free ARV treatment encourages people to get tested for HIV

Providing free treatment creates an incentive for people to get themselves tested. Without treatment options that include ARV drugs, a positive HIV result is notice of one's impending death. With effective treatment, a positive test result signals the beginning of a process where one must manage a powerful disease, but can still look forward to a healthy and productive life.

A U.S. study in the mid-1990s found that a major reason respondents did not get tested was they felt nothing could be done for them if they were positive. By 1998-99, with more widespread use and publicity of ARV drugs for treatment, fewer people cited this as a reason not to get themselves tested.[121]

A comprehensive treatment programme decreases the likelihood of transmission, by educating those infected about how to avoid transmission while at the same time decreasing their viral load

Some have argued that those being treated with ARV drugs may engage in increased high-risk behaviour, under the false belief they can no longer transmit the virus. A systematic review of the scientific literature finds, however, that those being treated with ARV drugs are no more likely to engage in high-risk behaviour than those who are not, and several studies suggest ARV treatment may correspond with a decrease in high-risk behaviour due to the education and counselling given when treatment is provided.[122]

Without a national comprehensive HIV/AIDS treatment programme, individuals are likely to seek treatment in the private sector where

120 *"The World Health Report 2004: Changing History"* published by the World Health Organisation p. 23

121 *"HIV Testing within At-Risk Populations in the United States and Reasons for Seeking or Avoiding Testing" Journal of AIDS*, 2002, Scott Kellerman and others

122 *"Highly Active Antiretroviral Therapy and Sexual Risk Behavior: A Meta-analytic Review"* Journal of American Medical Association, July 2004, Nicole Crepaz and others, conducts a systematic review of the scientific literature and comes to these findings

they may receive incomplete treatment, or be forced to stop treatment because of price, increasing the likelihood of drug-resistant HIV strains developing

If PLHA do not receive treatment through a national comprehensive HIV/AIDS treatment programme, those who can afford to are likely to turn to the private sector for treatment. Anecdotally in India, many private sector doctors inaccurately prescribe ARV drugs by e.g. prescribing mono-therapy instead of triple therapy, or prescribing drugs for incorrect periods of time. Further, many patients start ART, but without the required financial resources have been forced to stop therapy. Such instances are particularly serious because they allow the HIV virus to become resistant to cheaper and often more effective first-line ARV drugs.

If a PLHA with a drug-resistant strain of the virus transmits the virus to another person, that second person will also have a drug-resistant form of HIV.[123] The spread of such drug-resistant forms of HIV makes treatment much more expensive and medically serious for all concerned.

Numerous studies in Africa have shown that even in very resource-poor settings, adherence to drugs can be as high - if not higher – as in richer countries such as the United States or Western Europe. Such high adherence rates can only be achieved, though, where there is routine medical care, free or affordable ARV drugs, and free laboratory testing.[124]

In 2001, 6.6% of new infections in Brazil involved drug resistant strains, one third to one half of that found in North America or Western Europe. This result was founded on guarantees of long-term treatment, continuous training of health care personnel, use of standardised guidelines, and the involvement of non-Governmental organisations in promoting adherence.[125]

123 "*Modifying HIV antiretroviral therapy regimes*" Up-to-date Online, accessed 8/17/05, explains that drug resistance – "virologic failure" – is most commonly caused by poor adherence to ARV therapy

124 "*Adherence to HIV antiretroviral therapy in HIV+ Ugandan patients purchasing therapy*" International Journal of STD & AIDS, April 2005, J. Byakika-Tusiime and others.
"*Barriers to antiretroviral adherence for patients living with HIV infection and AIDS in Botswana*" appearing in Journal of AIDS, Nov. 2003, by Weiser and others
"*Economists', public health experts' and policy makers' declaration on free treatment for HIV/AIDS*" 2004, available www.re-so.net/spip.php?page=article_pdf&id_article=393

125 Note 120, *supra*, at 23

Untreated PLHA are susceptible to opportunistic infections, treatment of which costs the Government money

Their compromised immune systems mean that PLHA are highly vulnerable to opportunistic infections such as tuberculosis (the most common opportunistic infection in India) and pneumonia. Therefore, in combating diseases such as tuberculosis in India, it is important to provide treatment to PLHA, to reduce their risk of developing these opportunistic infections, which can also affect HIV negative persons.

A national comprehensive treatment programme will save the government and Indian economy money - anything less could prove economically disastrous

HAART treatment reduces morbidity and mortality rates amongst PLHA.[126] In Brazil, the introduction of ART saved the Brazilian Government money in the long-term, by averting deaths and reducing the number of hospital admissions. According to the World Health Organisation "*From 1996 to 2002* [in Brazil], *more than 60,000 HIV/AIDS cases, 90,000 deaths, and 358,000 HIV/AIDS-related hospital admissions were averted, and the savings in outpatient and hospital costs have outweighed the costs of implementation by more than US $200 million in four years.*"[127]

Currently, India pledges to treat all opportunistic infections for free (confirmed in the Union of India's Counter Petition in the *Voluntary Health Association of Punjab* case, at p. 314). As NACO itself accepts, a "*[l]ower frequency of opportunistic infections significantly reduces the cost of management of HIV.*" (Draft NACO Guidelines p. 324).

In addition to savings in healthcare, there are large savings available to the economy in fully treating PLHA, as the Supreme Courts in Costa Rica and El Salvador have pointed out (see Chapter 4 below). Most PLHA are in the prime working years of their life. By providing treatment, those who would have died or fallen sick from HIV/AIDS-related diseases are able to continue working and raising families.

126 "*Highly Active Antiretroviral Therapy Decreases Mortality and Morbidity in Patients with Advanced HIV Disease*" Annals of Internal Medicine, July 2001, Edward Murphy and others

127 Note 120, *supra*, at 23

CHAPTER 5

Important PILs in India on HIV/AIDS treatment

The Human Rights Law Network and other civil society groups and individuals have filed many Public Interest Litigations in Indian Courts on the issue of HIV/AIDS. These petitions have been very successful in many Courts in the country, where the active Indian Judiciary has recognised and upheld the rights of PHLA under the Constitution of India.

Voluntary Health Association of Punjab v Union of India

"Does the Government have the right to play with our lives? Are we puppets?"

Jehanabi Goswami, Assam Network of Positive People.
(AIDS INDIA eForum, 15 August 2007)

Until recent times, HIV infection meant a rapid countdown towards death as it developed into AIDS. However, the development of ARV drugs has resulted in the increased ability of positive people to attain a remarkably enhanced lifespan with many more healthy years.

Until 2004, though, a positive person in India could receive no such therapy in any Indian public hospital free of cost, and was simply left to die unless they could afford to buy it. Indeed, the Government had stated in its National AIDS Control Policy that it could not provide support for such treatment as it was "prohibitively expensive."[128] Given the fact that a huge number of positive people in India are positioned in the poorer economic strata, there existed large-scale dependence on a public health system that was totally unconcerned with their plight.

128 http://health.groups.yahoo.com/group/saathii/message/466

In recognition of the right to treatment and to health of PLHA, Human Rights Law Network on behalf of the Voluntary Health Association of Punjab filed a Public Interest Litigation referred to as *Voluntary Health Association of Punjab v. Union of India,*[129] in October 2003 in the Supreme Court of India, calling upon the Government to provide universal access to treatment. The petition set out to address violations of the right to equality and the right to life set out in Articles 14 and 21 of the Indian Constitution, and to significantly amend the National AIDS Control Policy of the Government of India. The Petitioner claimed that the total indifference and disregard for the lives of positive persons in India was against all the established principles of human rights jurisprudence.

Along with the petition brought by the Voluntary Health Association of Punjab, the Supreme Court had been moved by three other Petitioners: Sahara House, Sankalp Rehabilitation Trust and Common Cause. At the outset, these petitioners called on the Government to ensure that treatment was not refused in Government hospitals to PLHA. The VHAP petition was the only one which raised the issue of provision of ARV drugs by the government. The VHAP and HRLN faced some criticism from certain quarters, suggesting they ought not to have brought the case for treatment, saying the Government had insufficient money to fund treatment as well as prevention, and that it was correct for the bulk of Government spending to go on prevention. VHAP and HRLN thought this argument should be made by the Government, not civil society.

To the benefit of PLHA living in India, all petitioners have now taken up the issue of access to ARV drugs (as well as access to general treatment in healthcare institutions) and there is now some kind of unanimity of views amongst those fighting for the same cause. We are now fighting a uniting battle for services, access to treatment and protection of dignity and rights of all people in India affected by HIV/AIDS.

Petitioner's Arguments

The Petitioner noted the outward impression given by the Government of India that it had intentions of providing care and treatment to PLHA, but highlighted the Government's ambivalent attitude towards treatment by anti-retroviral therapy. The Petition drew on international treaties and

129 Writ Petition (Civil) No. 311 of 2003, Supreme Court of India

jurisprudence to highlight the gap between the Government's outward commitment to human rights and its actual lack of provision of healthcare facilities for PLHA. The Petition drew attention to the proceedings of the twenty-sixth Special Session of the General Assembly of the United Nations, from 25 to 27 June 2001. India is a signatory to the Resolution adopted in this Special Session which outlines the intention that, by 2003, signatories must address factors affecting the provision of HIV-related drugs, with particular regard to affordability and pricing. The Petition highlighted the Indian Government's failure to do so.

It was asserted by the Petitioner that the Supreme Court has held that the plea of financial inability has no juridical basis as far as the non-negotiable facets of human rights are concerned. Evidence was submitted of middle income, developing countries where the Government has provided free of cost treatment to positive people. In such countries, a certain containment of the epidemic has occurred. It was strenuously pleaded that the position of the Indian Government, in effectively blocking off treatment and the ensuing right to life of the millions of positive people, stands against all tenets of humanitarianism and civilisation.

The Petitioner prayed that the Government be directed to provide free and equitable access to anti-retroviral treatment to PLHA under the public health system. Furthermore, a direction seeking the Government review the National AIDS Control Organisation was also included. Also sought was a direction that the Government should create infrastructure in public health institutions, including trained doctors and paramedics. The declaration of a national emergency and the invocation of the compulsory licensing provision under the TRIPS agreement, so that the prices of the anti-retroviral drugs can be decreased, were also included in the Petition. Additionally, a direction was sought which could oblige the Government to raise and commit the required financial resources as identified by the UNGASS Declaration adopted by the UN 26th Special Session in June 2001, by the year 2003.

Government's Response

In response to the VHAP Petition, in December 2003, the Government of India announced a policy for providing anti-retroviral treatment to 1,00,000 people living with HIV/AIDS, free of cost, with implementation

starting on 1 April 2004.[130] The goal of the programme as outlined in the draft NACO guidelines was essentially to place 1,00,000 PLHA on structured ART by the end of 2005, and to be able to provide additional treatment to 15-20% of PLHA each year thereafter, for a period of five years.[131] The Government created a new target of treating 1,00,000 by 2007 after realising it would not meet its 2005 goal. As of November, 2006 a total of 32,000 people[132] were on ARV drugs in India whereas UNAIDS estimated there were 7,85,000 people in India who require ART treatment as of August 2005.[133] Although the last few years have marked definite progress, universal access to ARV drugs remains elusive to thousands of positive people in India.

Several further rounds of submissions have been made in the VHAP case, drawing on data gathered by the Petitioner at a number of national consultations (the reports of which form the basis of Chapter 6 of this book).

Petitioner's Demands

In the first week of September 2005, an affidavit was filed in the PIL, containing testimony of positive people from thirteen states making painfully clear the dire need for free ARV drugs, and on the basis of these the following directions have been sought:

A. The Government must immediately train doctors, nurses, and counsellors on a large-scale national basis, to provide a comprehensive HIV/AIDS treatment programme which includes the administration of ARV drugs, in at least every district hospital in India.

B. The Government must provide access to ART (with at least one second-line option), required counselling and testing (including but not limited to CD 4 testing, complete blood count, liver function tests, kidney function tests – BUN and creatinine - and a

130 Note 9, *supra*

131 Ibid., at 370

132 Human Rights Law Network and Voluntary Health Association of Punjab Report on the two day consultation on ARV Treatment held on the 14th-15th October, 2006. http://www.hrln.org/admin/issue/Pdf?file/20061110072724_Binder1.pdf

133 UNAIDS and WHO. *Progress on Global Access to HIV Antiretroviral Therapy*: A Report on '3 by 5' and Beyond", March 2006. http://www.who.int/hiv/progreport2006_en.pdf, at page 73

lymphocyte count), nutritional support, and medicines needed to treat opportunistic infections in every district hospital. Paediatric formulations and specialised care should be available for HIV infected children.

C. PLHA should be issued with Antyodaya Anna Yojana ("AAY") Cards so they can receive subsidised food. The Government must design such a programme to ensure the greatest degree possible of confidentiality to those using it.

D. PLHA should be given free Government train travel so they can access HIV/AIDS treatment centres. The Government must design such a programme to ensure the greatest degree of confidentiality possible to those using it.

E. The Government must provide trained doctors and counsellors to administer the treatment programme in a non-discriminatory manner. These doctors and counsellors must be given clear instructions on treating patients with care and dignity, and to respect their rights. They must also maintain confidentiality about the patient's HIV status. The Government must effectively monitor doctors and counsellors to ensure these instructions are carried out.

F. The Government must provide free ART along with the other requisites of HIV/AIDS treatment to accredited doctors in the non-profit and private sector, as well as a reasonable fee for their services in order to speed up and widen access to care options for PLHA needing ARV treatment. The Government must monitor the doctors to ensure they give high quality care to patients and do not charge the patients for the free drugs.

G. The Government must widely publicise the availability of the Government's free treatment programme in radio, print, and television media.

H. The Government must move quickly to access available international sources of funding for its ART programme.

I. The Government must formulate and implement a system wherein there is proper and timely monitoring and evaluation mechanisms to ensure that ARV treatment is given along NACO guidelines.

J. All money directed towards the HIV/AIDS treatment programme must go before the Comptroller and Auditor General (CAG) to ensure its proper handling and disbursement and transparency should be maintained at every level of programme implementation.

A semi-annual report should be published by NACO detailing the progress of the ARV rollout (including but not limited to giving the names of active treatment centres, how many people are receiving drugs, the ARV rollout programme's budget, what problems have arisen in the programme and how they are being dealt with, and the next steps of programme implementation). The PLHA community should be involved in each step of this process.

K. The Government must pass regulations to ensure new ARV drugs can be quickly and compulsory licensed to ensure affordable generic ARV medicines in the future.

L. The Government cannot use its duty to treat PLHA as an excuse to under-fund other prevention efforts.

The Petition and these directions came before the Supreme Court for hearing in August 2006, before Chief Justice Sabharwal. The Court asked Central Government to explain its position, and to explain why it had failed to meet its target of providing free ART for 1,00,000 HIV positive people by 2005. At the time of the hearing, it was estimated that of the 5 million affected persons[134] living in India, at least 5,00,000 needed ARV treatment immediately, but only 32,000 were actually receiving treatment.

Petitioner's Proposed Draft Directions

The Second National Consultation on ARV treatment was therefore called, to discuss the demands of PLHA. 27 draft directions, drawing on those previously submitted, were thoroughly discussed in this meeting (for further report of the outcomes of this meeting, please see below). These draft directions were placed before the Supreme Court:

1 There should be universal ART treatment for all PLHA requiring ART by the end of 2007. According to NACO, there were about 5 lakh persons requiring ART in 2003. Today only about 36,000 are said to receive ART.

2 The ARV drugs should be distributed in every district hospital in India.

3 Paediatric formulations for all HIV+ children requiring ART be made available by end 2006. 10% of all PLHA are children.

134 This figure has since been revised

4 The Government must immediately train and/or hire doctors, nurses, community health workers, and counsellors on a large-scale national basis to provide a comprehensive AIDS treatment programme, which includes the administration of ARVs, in at least every district hospital in India. A system of referral must be put in place to larger hospitals to ensure proper management of more complicated cases.

5 The Government must provide free ARV drugs along with other requisites of HIV/AIDS treatment to accredited doctors in the non-profit and private sector, as well as a reasonable fee for their services in order to speed up and widen access to care options for HIV positive persons needing ARV treatment. The Government must monitor the doctors to ensure they give high quality care to patients and do not charge PLHA for free drugs.

6 NACO must revise the first line regimen to include those drugs recommended by WHO, including, Abacavir, Tenofovir and Emtricitabine.

7 Tenofovir, abacavir, emtricitabine, and didanosine should be made available for use as second-line drug replacements for patients who have failed their current zidovudine- or stavudine-based ART regimen. These drugs should also be made available for use in first-line ART regimens for patients who have adverse effects from zidovudine or stavudine, or for patients for whom zidovudine and stavudine are contraindicated in the first line regimen (e.g. due to baseline anaemia).

8 Prevention of parent to child transmission (PPTCT) of HIV should be scaled up to the whole country.

9 All healthcare workers must be provided with a safe working environment, to include provision of protective gear, ARV to be provided free in the case of needle pricks, and special passes for free and unrestricted movement in conflict situations.

10 Adequate stocks should be maintained, particularly in remote regions, so there is no interruption in supplies under any circumstances. Realising that any interruption in the supply of drugs may mean resistance, and ultimately death for the consumer, strict disciplinary action must be taken in cases of interruption in supply.

11 Public Sector companies such as IDPL, RDPL, HAV, KAPL and BCPL be directed to begin manufacturing of ARV drugs.

12 All taxes and duties on ARV drugs be immediately removed.

13 The Government should provide the protease inhibitors lopinavir/ritonavir, indinavir, nelfinavir, and atazanavir.

14 NACO must put in place and implement effective monitoring and evaluation mechanisms to ensure that ART is given along NACO guidelines.

15 The Government must provide required testing for ART, and treatment of OIs, free of cost (including but not limited to CD4 count testing, complete blood count, liver function tests, kidney function tests (BUN and creatinine), a lymphocyte count, and tuberculosis testing) in every district hospital by the end of 2007.

16 NACO must build an enabling environment to ensure that people voluntarily come forward for counselling and testing on the basis of informed consent, without fear of stigma and discrimination or breach of confidentiality. The voluntary counselling and testing centres must recruit PLHA in preference to other person.

17 The Government of India must draw up guidelines that have doctors throughout the public health system ask their patients if they would like to be tested for HIV. If patients decline the offer of the test, the patient's wishes should always be respected. More routine testing throughout the public health system will ensure HIV is diagnosed earlier, thereby slowing the spread of the disease and aiding in the early treatment of those who test positive.

18 The Government must provide medicines needed to treat opportunistic infections, as well as medications that serve as primary and secondary prophylaxis for OIs, in every district hospital. Such treatment should include, but not be limited to those listed in Table 3 below:

Table 3

HIV-associated illness	Treatment (including prophylaxis)
Oropharyngeal candidiasis	Anti-fungal oral drops for oral involvement; fluconazole for esophageal involvement
Pulmonary tuberculosis	Isoniazid, rifampicin, pyrazinamide, and ethambutol
Extrapulmonary tuberculosis	Isoniazid, rifampicin, pyrazinamide, and ethambutol

HIV-associated illness	Treatment (including prophylaxis)
Pneumocystis carinii pneumonia	Cotrimoxazole double strength for treatment, primary prophylaxis, and secondary prophylaxis
Cryptococcal meningitis	Amphotericin B/flucytosine and fluconazole for treatment of acute infection; fluconazole for secondary prophylaxis
Herpes simplex/Herpes zoster	Acyclovir for severe cases, as well as for meningitis
Cryptosporidial and Isospora belli diarrhea	Cotrimoxazole and nisonide-O for treatment, cotrimoxazole for primary prophylaxis
CNS toxoplasmosis	Pyrimethamine/sulfadiazine for treatment, cotrimoxazole for primary prophylaxis
Cytomegalovirus retinitis	Intraocular ganciclovir injections; intravenous ganciclovir for refractory cases
Tinea (fungal) skin infections	Appropriate antifungal creams, and systemic fluconazole or itraconazole as required
Recurrent bacterial pneumonias	Antibiotics with appropriate coverage of specific infections, including ceftriaxone

19 The Government must ensure that HIV inpatient wards have appropriate precautions to prevent the spread of OIs amongst patients being treated in these wards. This is especially important in the context of tuberculosis, where studies have shown that multi-drug resistant and extreme drug resistant strains can spread easily among PLHA in inpatient wards. The Government must therefore ensure appropriate precautions are in place in these wards, including proper ventilation of wards, availability of tuberculosis masks for patients and healthcare workers, and regular disinfection of wards, to prevent patients from being harmed. Cotrimoxazole prophylaxis has been proven to be a simple and cost-effective intervention that greatly reduced the incidence of pneumocystis carinii pneumonia, CNS toxoplasmosis, HIV-associated diarrhea, and other OIs.

20 That all HIV+ persons be given free bus and train travel facilities along the lines of the concessions available to people with disabilities.

21 Nutritional supplements should be given to PLHA who cannot afford proper nutrition. These supplements should be based on the latest medical standards and vary depending on factors such as the age of the HIV positive person, whether they are on ART, whether they are being treated for particular HIV-associated infections (which can further exacerbate malnutrition), if they are pregnant, or if they have anaemia. The Antyoda Anna Yojana ("AAY") Card must be given to every family having a PLHA.

22 The majority of PLHA earn about Rs. 2000/ per month. International Labour Organisation studies have shown that expenditure on medicines is higher than that on food. World Bank studies indicate that expenditure on food was half that on medicines.

23 That the Comptroller and Auditor General of India be requested to report on how the money is available in the country for HIV+ people has been used. Government of India receives grants from the World Bank, Global Health Fund, and other international donors. These funds are not being accessed properly and used.

24 That the orders of the Supreme Court and the facilities available for HIV+ people be publicised widely on AIR and Doordarshan.

25 The Government must pass regulations so new HIV/AIDS drugs can be quickly and compulsory licensed to ensure affordable generic AIDS medicines in the future.

26 The Government must ensure tighter regulation of quack doctors who claim to provide "cures" for HIV disease and often charge patients exorbitant prices for these therapies, while delaying patients' access to appropriate medical care for HIV.

27 According to the new March 2006 UNAIDS report (http://www.who.int/hiv/progreport2006_en.pdf) UNAIDS estimated there are 7,85,000 people in India who require ART treatment as of August 2005 so the 7,80,000 number currently cited is out of date.

This submission sought important direction with regard to ARV treatment and ancillary problems faced by PLHA. It required the Government to provide access to ART with at least one second-line option.[135] The

135 Drug combinations that incorporate protease inhibitors are considered second-line drugs. These second-line drug combinations can be used if the virus develops a resistance to first-line drugs. The Indian Government currently provides second-line drug therapy only to those in need of it living near two pilot programme locations, one in Mumbai and one in Tamil Nadu

Government refuses to provide second-line drugs when patients develop resistance to first line ART, thereby condemning them to die if they cannot afford second line treatment elsewhere. The second line drugs sought in these directions are well-tested and effective. Developing countries such as Brazil and South Africa both provide second line therapy to those who have developed resistance to first line drugs.[136] As NACO has commented, "*In the event of treatment failure, a number of second line regimens have been found to be effective in prolonging the benefits of ART.*"[137]

Further, a comprehensive national treatment programme must include counselling and regular follow-ups with medical professionals to educate those receiving ART about the risk they still pose in transmitting the virus, despite their decreased viral load. Such measures ensure the rate of new infections of HIV will decrease. Hence, the directions sought counselling and testing in every district hospital.

ARV drugs need to be taken with adequate nutrition for optimum effectiveness. The Government was not providing information about nutrition, nor were they helping supplement the diets of those in need.[138] The directions therefore sought PLHA be issued with Antyodaya Anna Yojana Cards.

People who are receiving ART have to attend the district headquarters hospital to pick up their quota of ARV drugs for the month. This means losing one day's wages, as well as paying for the travel up and down and food. It may not seem like a lot of money, but if you are a daily wage labourer, it will be a huge expense. Hence, the directions sought demanded that all PLHA be given free bus and train travel facilities along the lines of the concessions available to people with disabilities and other chronic illnesses.

In February 2008, the case came up for hearing again before the Supreme Court of India. VHAP's counsel argued before the Supreme Court that

136 http://www.doh.gov.za/docs/factsheets/guidelines/artguidelines04/sec1.pdf "*Section 1: Antiretroviral Treatment (ART) in Adults*" details the South African Government's provision of AZT/ddi/l.PV/r – Zidovudine, Didanosine, Lopinavir/Ritonavir – which is a second-line therapy that includes a protease inhibitor to be used in case of resistance to first-line therapy options

137 Note 9, *supra*

138 Still, AAY cards are not yet distributed to PLHA, although the Ministry of Health has on 26 August 2008 written to the Ministry of Food & Public Distribution requesting AAY cards be provided to all PLHA

the ARV roll out programme was unsuccessful in many states. For instance, in the State of Orissa, there was only one CD4 count machine for the entire State, and that machine had been dysfunctional for the last six months. After hearing counsel for the Petitioner, the Supreme Court directed the Government Counsel to hold a consultation with the Petitioner NGOs, and submit a report to the Court after one month.

Petitioner's Further Proposed Directions

After a series of consultations with the counsel for the Government, NACO officials and other NGOs such as Common Cause, INP+ and Lawyers' Collective, the Petitioner submitted further draft interim directions. The directions submitted were as follows:

1 Union of India shall establish a minimum of 173 functional ART centres by March end 2008. All category A & B districts shall be covered with ART centres established by that date.

2 There shall be one link centre in every district by the end of 2008 and a minimum of 677-link centres in the country by the end of 2008.

3 Every HIV + person will be provided with a free travel facility.

4 Every HIV + person will be provided with an AAY Card.

5 Government of India will ensure that opportunistic infection medicines, in accordance with the NACO lists, will be available free for all PLHA without any difficulty.

6 Government of India will ensure that testing kits will be available without any shortfall.

7 Government of India and all the State Governments shall ensure that in all Public Hospitals, PHCs, CHCs and the like, PEP equipment and material shall be provided to all doctors, nurses and hospitals staff so that under no circumstances is a PLHA denied treatment on the ground that such equipment and material are not available.

8 All doctors and nurses in the public and private sector are directed to immediately familiarise themselves with the NACO protocols and policies. All doctors, nurses and hospital staff, whether in the public or private sector shall treat PLHA in a professional and humane manner, treating them always with dignity and care. No doctor or nurse shall refuse to treat a PLHA on account of his or her positive status. In treating a PLHA there shall be no discrimination or stigma whatsoever.

9 Doctors in the private sector, in particular are directed to immediately familiarise themselves with NACO's comprehensive protocols and policies with regard to care and treatment. Under no circumstances should they prescribe drugs other than strictly in accordance with the regime prescribed by NACO. The Medical Council of India and the Consumer Court are to take a strict view of private practitioners who take advantage of illiteracy and poverty to prescribe wrong or unnecessary regimes of drugs, or charge exorbitant amounts.

10 ART centres will be maintained by the Central and State Governments in a clean and hygienic manner, and shall provide clean drinking water, seating arrangements and clean toilet facilities to all PLHA.

11 Government of India and State Governments shall strictly abide by NACO's policies and guidelines regarding counselling. Counselling will be done in a meaningful manner, spending time on each individual PLHA in an atmosphere that is private and confidential.

12 Second line treatment shall be provided by Government of India to a minimum of 3000 persons by the end of 2008. This facility should be available even to those receiving private ART today.

13 The NACO helpline shall be operational immediately, including mobile phone facility, involving PLHA, NGOs and others in the provision of substantial information.

14 In addition to 69 CD-4 count machines, 64 new machines will be operational by April 2008. NACO will ensure that by the end of 2008, facilities will be placed in all link centres to collect samples on a regular and convenient basis to be sent to CD-4 count machines for testing.

15 All PLHA shall be provided with a job card and employment in accordance with the NREGA scheme.

Government's Most Recent Proposed Directions

On 5 August 2008 the Government of India submitted to the Indian Supreme Court a list of proposed commitments, which have been approved by the Supreme Court. These commitments make provisions for PLHA in India to receive treatment, economic and other support (as set out below).

1 At present, 172 ART centres are functional. All category A & B districts shall be covered in a phased manner and ART centres shall be established in these districts.

2 A plan for link ART centres has been formulated and put into operation by NACO. NACO is directed to ensure that all districts which have a critical mass of patients on ART shall have a link ART centre. NACO shall ensure that 650 Link ART centres shall be made functional by 2010.

3 Presently 139 CD4 machines are installed in the country to take care of 172 centres, by way of a sample transport mechanism for centres without CD4 machines. The sample is transported by the lab technician who brings back the report also after testing at the nodal centre. NACO has also entered into a comprehensive maintenance contact with effect from May 2007 with an agency for maintenance of the CD4 machines and stringent damage clauses have been inserted to ensure that repair and maintenance of these machines is done in a timely and efficient manner. The facilities shall be extended by NACO as more centres are opened up and the sample transport mechanism will be further expanded.

4 ART centres will be maintained by the Central and State Governments in a clean and hygienic manner and shall provide clean drinking water, seating arrangement and clean toilets facility to all PLHA.

5 NACO and all State Governments are directed to immediately create a mechanism for redressal of grievances at ART centres. NACO shall post the names and contact details of its Regional Coordinators as well as the Nodal Officers heading an ART Centre on its website and these will be made available to INP+ also. Further, a committee will be constituted in every State, to be chaired by the Secretary, Health of the State Government/Medical Education and consisting of among others, representatives of PLHA networks; this committee shall meet every quarter and act as a grievance redressal mechanism. This mechanism will ensure that issues such as improper facilities, shortage of medicines, non-functioning of machines, delays etc are brought to the attention of the Nodal Officer, Regional Coordinator as well as NACO in a systematic manner for timely response.

6 Second line treatment is in the pilot stage; however, this program shall be expanded by NACO to ensure access to all those who are technically eligible as per roll out plan.

7 Union of India is directed to ensure that drugs for treatment of Opportunistic infections, in accordance with the NACO lists, will be available free for all PLHAs without any difficulty.

8 Union of India is directed to ensure that testing kits shall be available without any shortfall.

9 The NACO help line shall be made fully operational at the earliest.

10 All patients travelling to an ART centre for treatment shall be provided with free transport on the day they are going to the nearest ART centre. The state Governments are directed to evolve a mechanism for the same and to report compliance within a period of six weeks.

11 Union of India and all the State Governments shall ensure that in all Public Hospitals, PHCs CHCs and the like, PEP drugs and material shall be provided to all Doctors, nurses and hospitals staff so that, under no circumstances, is a PLHA denied treatment on the ground that such equipment and material are not available. The State Governments shall ensure that all health workers are provided a safe working environment and that PEP will be easily accessible and available.

12 All doctors and nurses in the public sector and the private sector are directed to immediately familiarise themselves and comply with the protocols and policies as prepared by NACO. The Medical Council of India, Dental Council of India and the Nursing Council of India shall take steps to disseminate the NACO protocols and policies on their respective websites as well as on the websites of the State Medical and Nursing Councils. Further the Medical Council of India as well as the Nursing Council of India shall ensure that these protocols are made part of the teaching curriculum/reading material at the disseminated to all Medical and Dental colleges as well as other institutions for training of nurses and other health care professionals. The Medical Council of India, Dental Council of India and the Nursing Council of India are directed to file a compliance report within six weeks.

13 All Doctors, nurses and hospital staff, whether in the public sector or private sector shall treat PLHA in a professional and humane manner, treating them always with dignity and care. No doctor or nurse shall refuse to treat a PLHA on account of his/her positive status. In treating a PLHA, there shall be no discrimination or stigma whatsoever.

14 Doctors in the private sector, in particular, are directed to immediately familiarise themselves with the NACO's comprehensive protocols

and policies with regard to care and treatment, which are available or NACO website. NACO approved ART regimen have proven to be cost effective, safe and PLHA have shown good response to these regimen. The private practitioners should use these cost effective regimen in the first instance and other regiments should be prescribed only in cases where these cannot be used for the reasons of toxicity/ failure etc. the Medical Council of India and the Consumer Courts are to take a strict view of private practitioners who take advantage of the illiteracy and poverty to prescribe wrong or unnecessary regimes of drugs or charge exorbitant amounts. Irrational prescriptions using wrong dosages/wrong combinations shall be dealt with severely and appropriate action taken.

15 The State Government shall strictly abide by NACO policies and guidelines regarding counselling. Counselling will be done in a meaningful manner, spending time on each individual PLHA in an atmosphere that provides privacy and confidentiality.

16 Union of India/State Governments are directed to ensure that every HIV+ person on ART shall be provided with an Antodaya Anna Yojana Card.

17 Union of India/State Governments are directed to ensure that all PLHAs shall be provided with a job card and employment in accordance with the NRGEA scheme.

18 A status report shall be filed by NACO, which is directed to act as a nodal agency on behalf of the Government of India, before this court every three months on the steps taken by the Central Government pursuant to these directions.

19 All State Governments, Medical Council of India, Dental Council of India and Nursing Council of India shall file compliance reports as directed within six weeks.

Having made these proposed commitments, and them having been the subject of a Supreme Court order, the Government said it would now consult further with Governmental agencies, and prepare a Circular, detailing the implementation of these proposals.

On 1 October 2008, the Supreme Court passed an order directing all State Governments to comply with the orders contained in an Office

Memorandum issued by the Ministry of Health and Family Welfare and NACO, calling for implementation of the 19 point proposal (a full copy of the order and report is available from the HRLN website). The Ministry of Health also submitted to the Supreme Court a series of letters it had written to the various other Ministries and bodies responsible for implementation of the proposal, for example the Ministry of Food and Public Distribution, the Ministry of Road Transport and Highways and the Railway Board. NACO has been ordered to submit a status report to the Supreme Court within four months of the date of the order, and further updates will be published by HRLN and VHAP.

Critique

Whilst the 19-point proposal made by the Government is an important step, what was starkly lacking was commitments in relation to second line treatment, and the VHAP proposed to take this up in the next round of litigation. This was a very disappointing development. VHAP and HRLN also had reservations in relation to the number of ART centres and CD4 count machines – which again the VHAP planned to take up in the next round of litigation.

Table 4 below contains the critique of the 19-point Government proposal prepared following a large National Consultation with positive groups from across the country. The column on the right represents the suggested amendments proposed by the VHAP and the positive network representatives and highlights the deficiencies in the Government's proposal.

Table 4

NACO Proposal	Suggested Amendment
Point 1	
At present, 172 ART centres are functional. All category A & B districts shall be covered in a phased manner and ART centres shall be established in these districts.	At present, 172 ART centres are functional. All districts will have an ART centre in them and medical college facilities shall be maintained. Category A & B districts (which shall include any district ever classified as A or B) shall be covered first in a phased manner.

NACO Proposal	Suggested Amendment
Point 2	
A plan for link ART centres has been formulated and put into operation by NACO. NACO is directed to ensure that all districts which have a critical mass of patients on ART shall have a link ART centre. NACO shall ensure that 650 Link ART centres shall be made functional by 2010.	A plan for link ART centres has been formulated and put into operation by NACO. NACO is directed to ensure that all districts which have a critical mass of patients on ART shall have a link ART centre. NACO shall ensure that 650 Link ART centres shall be made functional by 2010.
Point 3	
Presently, 139 CD4 machines are installed in the country to take care of 172 centres, by way of a sample transport mechanism for centres without CD4 machines. The sample is transported by lab technician who brings back the report also after testing at the Nodal Centre. NACO has also entered into a comprehensive maintenance contract with effect from May 2007 with an agency for maintenance of the CD4 machines and stringent damage clauses have been inserted to ensure that repair and maintenance of these machines is done in a timely and efficient manner. The facilities shall be extended by NACO as more centres are opened up and the sample transport mechanism will be further expanded.	Presently, 139 CD4 machines are installed in the country to take care of 172 centres, by way of a sample transport mechanism for centres without CD4 machines. The sample is transported by lab technician who brings back the report also after testing at the Nodal Centre. NACO has also entered into a comprehensive maintenance contract with effect from May 2007 with an agency for maintenance of the CD4 machines and stringent damage clauses have been inserted to ensure that repair and maintenance of these machines is done in a timely and efficient manner. All ART centres will have a CD4 count machine. Every link ART centre will have collection facilities for CD4 count samples. Wherever there is a CD4 count machine or collection facility, kits and reagents shall be freely available without any shortfall.
Point 4	
ART centres will be maintained by the Centralised State Governments in a clean and hygienic manner and shall provide clean drinking water, seating arrangement and clean toilet facility to all PLHA	ART centres will be maintained by the Centralised State Governments in a clean and hygienic manner and shall provide clean drinking water, seating arrangement and clean toilet facility to all PLHA

NACO Proposal	Suggested Amendment
Point 5	
NACO and all State Governments are directed to immediately create a mechanism for redressal of grievances at ART centres. NACO shall post the names and contact details of its Regional Coordinators as well as the Nodal Officers heading an ART Centre on its website and these will be made available to INP+ also. Further, a committee will be constituted in every State to be chaired by the Secretary, Health of the State Government/Medical Education and consisting of among others, representatives of PLHA networks; this Committee shall meet every quarter and act as a grievance redressal mechanism. This mechanism will ensure that issues such as improper facilities, shortage of medicines, non-functioning of machines, delays etc are brought to the attention of the Nodal Officer, Regional Coordinator as well as NACO in a systematic manner for timely response.	NACO and all State Governments are directed to immediately create a mechanism for redressal of grievances at ART centres. NACO shall post the names and contact details of its Regional Coordinators as well as the Nodal Officers heading an ART Centre on its website and these will be made available to INP+ also. A mechanism will be set up as follows: • ***Accountability:*** District Aids Prevention and Control Units (DAPCU) shall be accountable at district levels; a committee accountable at a state level will be constituted in every State to be chaired by the Secretary, Health of the State Government/Medical Education and consisting of among others, representatives of PLHA networks. • ***Monitoring:*** A commissioner shall be appointed by the court at a national level, and the court-appointed commissioner shall appoint state-level staff responsible for monitoring implementation.. The state-level Committee shall meet every quarter and also act as a grievance redressal mechanism. This mechanism will ensure that issues such as improper facilities, shortage of medicines, non-functioning of machines, delays etc are brought to the attention of the Nodal Officer, Regional Coordinator as well as NACO in a systematic manner for timely response.

NACO Proposal	Suggested Amendment
Point 6	
Second line treatment is in the pilot stage, however, this program shall be expanded by NACO to ensure access to all those who are technically eligible as per roll out plan.	There has been a pilot programme for second line treatment. NACO will publish a report on the second line treatment pilot programme, which shall include such information as the reasons for carrying out the pilot programme, the number of people treated under the pilot programme and the results. Union of India is directed to ensure that second line treatment is available to all those who need it by the end of this year, free of cost and without any shortfall. Viral load and resistance testing should be available in every state.Union of India and State Governments are directed to ensure that there is no shortage of doctors trained to administer second line treatment regimens.
Point 7	
Union of India is directed to ensure that drugs for treatment of Opportunistic Infections, in accordance with the NACO lists, will be available free for all PLHAs without any difficulty.	Union of India is directed to ensure that drugs for treatment of Opportunistic Infections, in accordance with the NACO lists. will be available free for all PLHAs without any difficulty in the same places at which ARV treatment is available. In particular, Union of India is directed to ensure that antibiotics shall be available free of cost at all ART centres.
Point 8	
Union of India is directed to ensure that testing kits shall be available without any shortfall.	Union of India is directed to ensure that high quality testing kits shall be available without any shortfall.
Point 9	
The NACO helpline shall be made fully operational at the earliest.	The NACO helpline shall be made fully operational at the earliest.

NACO Proposal	Suggested Amendment
Point 10	
All patients travelling to an **ART centre for treatment shall be provided with free transport** on the day they are going to **the nearest ART centre. The** State Governments are directed to evolve a mechanism for the same and to report compliance **within a period of six weeks.**	All PLHA travelling to a healthcare centre for any testing, diagnostic or treatment purposes shall be provided **with free transport, together with one** attendant and any minor children. For **HIV positive pregnant women, this shall** include travel to access any pre-natal healthcare services. Transport shall be by **any of bus, train, water-based services or** ambulance facilities, and may be local or interstate. The State Governments are directed to evolve a mechanism for the **same and to report compliance within a period of six weeks.**
Point 11	
Union of India and all the State Governments shall ensure that in all Public Hospitals, PHCs, CHCs **and the like,** PEP drugs and material shall be provided to all Doctors, nurses and hospitals staff so that, under no circumstances is a PLHA denied treatment on **the ground that such equipment** and material are not available. The State Governments shall **ensure that all health workers are provided a safe working** environment and that PEP **will be easily accessible and** available.	**Union of India and all the State** Governments shall ensure that in all **healthcare settings, Universal Precaution kits and materials and PEP drugs** and materials shall be provided to all Doctors, nurses and hospital staff so that, under no circumstances is a PLHA denied treatment on the ground that such **equipment and material are not available.** The State Governments shall ensure **that all health workers are provided a safe working environment and that PEP will be easily accessible and available. Under no circumstances will the patient** be charged for or made to provide **the Universal Precaution or PEP kits,** medicines or materials.

NACO Proposal	Suggested Amendment
Point 12	
All Doctors and nurses in the public sector and private sector are directed to immediately familiarise themselves and **comply with the protocols and policies as prepared by NACO.** The Medical Council of India, Dental Council of India and the Nursing Council of India **shall take steps to disseminate the NACO protocols and** policies on their respective **websites as well as on the websites of the State Medical** and Nursing Councils. Further, the Medical Council of India shall ensure that these protocols are made part of the teaching curriculum/reading material at and disseminated to all Medical and Dental colleges **as well as other institutions for** training of nurses and other health care professionals. The Medical Council of India, Dental Council of India and the Nursing Council of India are **directed to file a compliance report within six weeks.**	All Doctors and nurses in the public sector and private sector are directed to immediately familiarise themselves and **comply with the protocols and policies as prepared by NACO. The Medical** Council of India, Dental Council of India and the Nursing Council of India shall **take steps to disseminate the NACO** protocols and policies on their respective **websites as well as on the websites of** the State Medical and Nursing Councils. Further, the Medical Council of India shall ensure that these protocols are made part of the teaching curriculum/ reading material at and disseminated to **all Medical and Dental colleges as well** as other institutions for training of nurses and other health care professionals. The Medical Council of India, Dental Council of India and the Nursing **Council of India are directed to file a compliance report within six weeks.**

NACO Proposal	Suggested Amendment
Point 13	
All Doctors, nurses and hospital staff, whether in the public sector or private sector shall treat PLHA in a professional and humane manner, treating them always with dignity and care. No Doctor or nurse shall refuse to treat a PLHA on account of his/her positive status. In treating a PLHA, there shall be no discrimination or stigma whatsoever.	All Doctors, nurses and hospital staff, whether in the public sector or private sector shall treat PLHA promptly and professionally and in a humane manner, treating them always with dignity and care. No healthcare provider shall refuse to treat a PLHA on account of his/her positive status. In treating a PLHA, there shall be no discrimination or stigma whatsoever. Any healthcare provider in breach of this direction shall have disciplinary action taken against him or her. Union of India and State Governments are directed to ensure that facilities are available in all district hospitals for positive women to give birth by Caesarean section. No woman shall be refused a Caesarean section delivery on the basis of her positive status. Every healthcare provider shall ensure that the confidentiality of his or her patient is protected. All healthcare providers shall, within a year of these directions, undergo training on the treatment of PLHA in accordance with NACO guidelines and protocols. Positive networks and PLHA shall have meaningful involvement in the preparation and execution of these training sessions.

NACO Proposal	Suggested Amendment
Point 14	
Doctors in the private sector, in particular, are directed to immediately familiarise themselves with the NACO's comprehensive protocols and policies with regard to care and treatment, which are available on NACO website. NACO approved ART regimen have proven to be cost effective, safe and PLHA have shown good response to these regimen. The private practitioners should use these cost effective regimen in the first instance and other regiments should be prescribed only in cases where these cannot be used for the reasons of toxicity/failure etc. The Medical Council of India and the Consumer Courts are to take a strict view of private practitioners who take advantage of the illiteracy and poverty to prescribe wrong or unnecessary regimens or drugs or charge exorbitant amounts. Irrational prescriptions using wrong dosages/wrong combinations shall be dealt with severely and appropriate action taken.	Doctors in the private sector, in particular, are directed to immediately familiarise themselves with the NACO's comprehensive protocols and policies with regard to care and treatment, which are available on NACO website. NACO approved ART regimen have proven to be cost effective, safe and PLHA have shown good response to these regimen. The private practitioners should use these cost effective regimen in the first instance and other regiments should be prescribed only in cases where these cannot be used for the reasons of toxicity/failure etc. The Medical Council of India and the Consumer Courts are to take a strict view of private practitioners who take advantage of the illiteracy and poverty to prescribe wrong or unnecessary regimens or drugs or charge exorbitant amounts. Irrational prescriptions using wrong dosages/wrong combinations shall be dealt with severely and appropriate action taken. The Union of India shall ensure that all unqualified quacks and bogus doctors shall be stopped from providing any treatment immediately. The Union of India is also directed to ensure advertisements for fake cures for HIV/AIDS are immediately stopped.

NACO Proposal	Suggested Amendment
Point 15	
The State Governments shall **strictly abide by NACO policies** and guidelines regarding counselling. Counselling **will be done in a meaningful** manner, spending time on each individual PLHA in an atmosphere that provides **privacy and confidentiality.**	The State Governments shall strictly **abide by NACO policies and guidelines** regarding counselling. Counselling **will be done in a meaningful manner**, spending time on each individual PLHA in an atmosphere that provides privacy **and confidentiality.** In particular, State Governments shall **ensure the following numbers of PLHA counsellors are maintained at ART** centres: • 1-500 people receiving treatment: 1 PLHA counsellor; • 501-1,000 people receiving treatment: 2 PLHA counsellors; • 1,001-1,500 people receiving treatment: 3 PLHA counsellors etc. **PLHA counsellors will receive a salary on par with that of other counsellors.**
Point 16	
Union of India/State Governments are directed to ensure that every HIV+ person **on ART shall be provided with an Antodaya Anna Yojana** Card.	**Union of India/State Governments are** directed to ensure that every HIV+ **person shall be provided with an** Antodaya Anna Yojana Card.
Point 17	
Union of India/State Governments are directed to ensure that all PLHAs shall be **provided with a job card and employment in accordance with** the NREGA scheme.	**Union of India/State Governments** are directed to ensure that all PLHAs **shall be provided with a job card and employment in accordance with the** NREGA scheme.

NACO Proposal	Suggested Amendment
Point 18	
A status report shall be filed by NACO, which is directed to act as a nodal agency on behalf of the Government of India, before this Court every three months on the steps taken by the Central Government pursuant to these directions.	A status report shall be filed by NACO, which is directed to act as a nodal agency on behalf of the Government of India, before this Court every three months on the steps taken by the Central Government pursuant to these directions.
Point 19	
All State Governments, Medical Council of India, Dental Council of India and Nursing Council of India shall file compliance reports as directed, within six weeks.	All State Governments, Medical Council of India, Dental Council of India and Nursing Council of India shall file compliance reports as directed, within six weeks.

Love Life Society v Union of India & Ors[139]

This case called for more CD4 machines to be made available in Delhi, and was filed in the Delhi High Court on behalf of a Positive Network in Delhi in 2006. The pleadings in the case argued that not providing adequate CD4 machines for testing PLHA is tantamount to depriving them of their fundamental right to life, enshrined in Article 21 of the Indian Constitution. Availability of adequate CD4 machines ensures anti-retroviral treatment can be administered to PLHA effectively, allowing for a normal, healthy and dignified life. The significance of the availability of CD4 machines is highlighted by the universal acknowledgement that prevention, care, support and treatment are mutually reinforcing elements of an effective response and have to be integrated in a comprehensive and effective approach to combat the existing HIV/AIDS epidemic.

Why are CD4 Machines Important?

HIV targets CD4 cells, a type of white blood cell that helps organise and coordinate the body's immune response to infections by signalling to immune cells to perform their unique functions. A person who has AIDS

139 High Court of Delhi, WP(C) No. 8700 of 2006

dies of the infections contracted as a result of the weakened immune system, not of the virus itself. PLHA are susceptible to e.g. pneumonia, diarrhoea, tumours and other illnesses that might pose a much lower threat to sero-negative individuals. A useful measure of progression of HIV in a person's body is the number of CD4 cells per unit of blood. AIDS can also be defined immunologically by a CD4 count of fewer than 200 cells/mm3 or a CD4 count higher than 200 cells/mm3 if the person is symptomatic i.e. also has certain other infections.

CD4 machines provide the basis for the eligibility of undergoing anti-retroviral therapy. To put it more plainly, if a PLHA cannot determine what his or her CD4 count is, he or she cannot determine whether ARV treatment is required, therefore exposing himself or herself to a great health risk. The CD4 test is done using the CD4 machine.[140] For those with a CD4 count of more than 500, tests need to be conducted every 6 to 12 months. At CD4 counts between 350 and 500, tests are performed every 3 to 6 months and when the count falls further, monthly or three-monthly tests are conducted to assess the progress of the disease and the effectiveness of the medicines.

Why was this case important?

At the time of filing the PIL, the availability of CD4 machines in Delhi was abysmally poor. Out of the six Government hospitals with anti-retroviral therapy facilities at their disposal, only three had CD4 machines. Whilst Lok Nayak Jai Prakash ("LNJP") Hospital and the Dr. Ram Manohar Lohia Hospital provided the test free of cost, A.I.I.M.S was charging Rs. 800 per test. Furthermore, while there existed a CD4 machine at the Safdarjung Hospital (costing Rs. 500 per test), this machine was dysfunctional most of the time. As there was only one CD4 machine in each of these hospitals, it is estimated that only 12-13 people were being tested per day. This led to a waiting list of 3-4 months, during which time the person seeking the test had no way to measure his/her CD4 count. People were dying as a result. It is not just people from Delhi seeking tests – people from Bihar, Uttar Pradesh and Haryana come to Delhi for tests, due to the poor testing facilities available in these states.

The petitioner prayed for the issuance of a Writ, Order or Direction directing the respondents to provide at least two CD4 machines in

140 This machine is a multi-functional diagnostic system, which is primarily used to count CD4 cells in PLHA, but it can also be used to detect leukaemia

each of the six hospitals having anti-retroviral therapy available. The petition also called on the Government to set up a committee to monitor CD4 machines, consisting of two positive persons from the Positive Network groups and Government representatives. The petitioner called on the Government to provide the CD4 test free of charge for PLHA and to create infrastructure in these public health institutions, including qualified and sensitive doctors and paramedics to handle the machines in a proper manner. In addition , the petitioner sought that the Government be directed to make it mandatory to carry out a CD4 test immediately after a HIV diagnostic test and, at the very least, to carry out such testing every three months for each positive person.

In November 2007, the High Court passed an order stating that treatment and testing services should be available to PLHA without delay or discrimination, and that the petitioner organisation, Love Life Society could carry the court orders to Hospitals in cases of denial of treatment.

A similar petition was filed in several States in India including Manipur, Bihar and West Bengal.

Mr. Wahengbam Joykumar v Union of India & Ors (Gauhati High Court, No. 7 of 2005)

This petition, before the Gauhati High Court, sought the provision of antiretroviral drugs to people living with HIV/AIDS in Manipur under the 'Free Antiretroviral Treatment Programme' established by NACO as a result of the VHAP case. The Petitioner is the Programme Executive of Human Rights Alert, a registered human rights organisation based in Manipur which, amongst other endeavours, strives for legal redressal measures to impact upon human rights issues in Manipur, including those affecting PLHA.

In Manipur itself, the prevalence of HIV/AIDS infection amongst injecting drug users has declined significantly in the last five years. However, according to the Manipur State AIDS Control Society, the prevalence among the general population is increasing.[141] Whilst the level of HIV/AIDS infection among drug users in 1997 was recorded at 80.7%, the level at the time of the petition was held to be 42%. However, over the same period, the rate of infection among the general population

141 *"Potential Impact of HIV among IDUs on heterosexual transmission in Asian settings: scenarios from the Asian Epidemic Model"*, International Journal of Drug Policy, Volume 14, Issue 1, Pages 63-74, T Saidal

was found to have risen from 1.97% to 2.80%. These trends were put down to (i) a decrease in the number of injecting drug users; and (ii) an increase in the number of cases of sexual transmission.

In an attempt to impact upon the effect of the disease, the National AIDS Control Organisation initiated the 'Free Antiretroviral Treatment Programme'. This Programme was launched in Manipur on 5 April 2004. The programme was commenced at the Regional Institute of Medical Sciences Hospital, where the ART Unit was meant to provide free drugs to 300 people. However, the inability of this unit to meet the needs of PLHA in Manipur, meant that on 1 December 2004, a second ART Unit was formed at the Jawaharlal Nehru Hospital, Porompat, with the intention of providing free ARV drugs to a further 200 persons.

Upon reading a report in the Sangai Express (English Edition) of 24 April 2005 entitled "ART drugs ceased at centers", the Petitioner travelled to the ART Unit of the RIMS Hospital during office hours on the two following days, only to discover that it remained closed on both days. Staff at the RIMS Hospital informed the Petitioner that the ARV Unit had been closed for many of the preceding days. Upon attempting to contact officials within the ART Unit at JN Hospital Porompat on 26 April 2005 during office hours, the petitioner found that Unit to be closed as well. Finally, on 28 April 2005, the Petitioner met with an official from the JN Hospital, Porompat. The Petitioner was informed that prior to the opening of the Unit, bulk provision of antiretroviral drugs was received from NACO through the Manipur State AIDS Control Society but that this stock was not replenished when it ran out. By February 2005, the ARV Unit did not have any of the antiretroviral drug Nevirapine in stock and, at the time of the petition, only two kinds of antiretroviral drugs were available from the Unit.

Given the inability of the Unit to provide PLHA with a complete regimen of antiretroviral drugs, it was necessary for PLHA to acquire the remaining drugs from the market, bearing the huge financial cost themselves. Allowing for the fact that a complete regimen of the necessary antiretroviral drugs is composed of at least three different drugs, the Petitioner learnt that the purchase of the necessary set of drugs at market prices cost between Rs. 940 to Rs. 2700 per month. Even when functioning fully, the capacity of the two Units was capped at 500, leaving hundreds of PLHA unable to afford the purchase of the necessary drugs on the waiting lists for these two Units.

Adherence to ARV therapy is critical to avoiding and/or delaying drug resistance. Gaps in supply of ARV drugs are therefore devastating for the health of those receiving treatment. The Petitioner approached the Court to enforce the right to medical treatment of PLHA, under the ambit of Article 21 of the Constitution of India.

The petition therefore called on the High Court to issue a writ directing the Respondents to provide the necessary antiretroviral drugs through the ART Units at the RIMS Hospital and the J.N. Hospital at the earliest possible opportunity. The Court was also asked to issue an appropriate direction to the Respondents to increase the capacity of the two ART Units in order to meet the needs of PLHA in Manipur. The High Court passed an order directing the Government to provide CD4 machines in more districts. The Order is available from the HRLN website. As a result of the issues set forth in the petition, much progress has been made in Manipur for the benefit of PLHA. Funds have been set aside to pay for medical treatment for people who cannot afford it. New equipment and machines have been procured and taken to previously underserved areas. Much more work needs to be done, but these are positive steps.

Delhi Network of Positive People & Love Life Society v Union of India & Ors (High Court of Delhi, No. 2885 of 2007)

A further Public Interest Litigation was filed in the Delhi High Court in 2007, demanding a 75% railway concession for HIV positive people in Delhi and the rest of the country.

The petition sought a writ directing the Government to include PLHA in the category of 'chronically ill persons' for railway travel concessions purposes. The petitioners sought no more than the implementation of Article 14 of the Constitution, stopping the denial to any person of equality before the law or the equal protection of the law within the territory of India. The Supreme Court has held in a plethora of judgments that every person in the country, within the right to life under article 21, has a right to health. Therefore, the Government is constitutionally obliged to ensure the same to all the persons residing in the country, including positive persons, who cannot be deprived of access to travel and medication in order to treat their condition.

To ensure adherence to ARV drugs and prevent, or at the very least delay, drug resistance, the ARV drugs need to be taken every single day. PLHA requiring treatment must therefore travel every month to receive their supply. Whilst these drugs are provided free of cost by the Government in the ART centres of each state, there were a maximum of two ART centres dispensing ARV drugs in states even as large as Rajasthan and Madhya Pradesh. Even then, the drugs are not always available at these centres and then there often exists a shortage of supply or an interruption in supply in certain areas. This forces PLHA to travel to neighbouring states for life-saving dosages of ARV drugs.

While NACO has highlighted that the majority of PLHA in India are from rural areas (57% in 2005),[142] most of the time rural people cannot travel to the districts where the ARV drugs are dispensed as the travel costs are too high. Once they have registered at a particular ART centre, PLHA face problems in obtaining treatment from other ART centres. As a tremendous number of positive people belong to the poor and under-privileged strata of society, travel costs are of critical significance. Thousands of HIV positive people faced with the high travel costs to and from the ART centres are often forced to forgo treatment in order to feed themselves and their families.

Given that most of the ART centres are located in the capital and metropolitan cities, most of the PLHA have to travel to the nearby cities. As mentioned above, Delhi is the converging point for people from neighbouring areas, and positive people from Bihar, Uttar Pradesh and Haryana come to Delhi for their treatment. This petition therefore sought a 75% travel concession for those travelling to receive treatment, together with one attendant.

Indian Railways provide a discount of 75% on the cost of tickets bought by those suffering from "chronic and incurable" diseases. This concession is extended to those suffering from the likes of tuberculosis, thalassemia, leprosy and cancer. People travelling for surgery are also given similar concessions. Heart patients alone or with escort (for both) are given a 75% concession. Kidney patients travelling for transplant dialysis are also given a 75% concession. Further, the railways have been providing concessions to unemployed youths, farmers and widows of defence personnel. Such concessions were announced in the Railway

142 http://www.expresspharmaonline.com/20080630/market04.shtml

Budgets for 2003-04, 2004-05 and 2005-06 respectively. In travelling to Delhi from states such as Bihar, Haryana, Uttar Pradesh, Rajasthan and Maharashtra, positive people have to incur a minimum cost of Rs. 1000 each time they seek treatment. The petitioner therefore sought the extension of the 75% concession offered to those suffering from illnesses such as tuberculosis, cancer and leprosy, to PLHA.

The Delhi State AIDS Control Society has recognised the need for a travel concession for PLHA travelling to Delhi or even to areas outside of Delhi for treatment. However, the response of the Railway Ministry to a request for such a concession has been that substantial revenue is being lost on account of the reductions that are granted to the various categories of persons and, with the financial constraints on the Railways in mind, a concession to the positive community is being denied. This approach is unhelpful at a time when inability to purchase travel every month to the medical centres translates into many deaths.

It was prayed that the Court pass an appropriate writ, order or direction directing the Government to introduce a scheme for the provision of a 75% concession to all the people living with HIV/AIDS requiring antiretroviral treatment and treatment for opportunistic infections.

The Hon'ble High Court ordered a meeting between Ministry of Health and the Railway Ministry to consider the issues and on 11 October 2007, Mr. Lallu Prasad Yadav, Ministry of Railway, announced 50% concession for PLHAs in the 2008 budget session.

Since then, NACO has announced, in its 19-point proposal in the *VHAP* case, that free travel should be available for all PLHA travelling to obtain treatment.

CHAPTER 6

The True Condition of the National ART Programme in India

The Voluntary Health Association of Punjab and the Human Rights Law Network have organised five National Consultations on Access to Treatment in India. These consultations have been attended by representatives from many HIV Positive Networks from across the country, and other stakeholders. The principal objective of these consultations was to have a detailed dialogue with members of the positive networks on access to ARV, OI treatment, the number of ART Centres, CD4 machines, PPCTC, VCTC, etc and gauge the nature of problems faced at a state and district level.

At each of the National Consultations, representatives from the positive networks have been invited to provide an up to date snapshot of the treatment situation in their state or district. To show the slow progress which has actually been made on the ground, despite the many promises made by the Government, the reports from each of the National Consultations are set out below. The information set out below is that information gathered from the positive network representatives and whilst efforts have been made to ensure the information is as **accurate as possible, no independent fact finding or investigation has** been carried out by HRLN.

First National Consultation

The first National Consultation was held in Chandigarh in September 2005. Table 5 demonstrates the situation of the national ART programme in India in the year 2004-2005, as reported by the representatives of the positive networks.

Table 5

STATES	No. of Districts	No. of ART centres	No. of CD4 machines.
Andhra Pradesh	23	2	1
Maharashtra	35	1	1
Tamil Nadu	30	4	2
Uttar Pradesh	70	2	1
Karnataka	29	3	1
Rajasthan	32	1	1
Orissa	30	NIL	NIL
Himachal Pradesh	12	NIL	NIL
Kerala	14	5	1
Manipur	9	2	1

The above-mentioned records were documented 17 months after the implementation of the national ARV roll out programme. Further information was provided on a state-wise basis by the delegates at the National Consultation.

Andhra Pradesh

- The total number of people in Andhra Pradesh estimated to be living with HIV/AIDS is reported as 5,00,000 as per the Andhra Pradesh State AIDS Control Society (SACS). The number of such persons eligible for ART was approximately 56,000. Out of 56,000 persons whose CD4 count had fallen below 200 and were therefore eligible for ART, only about 2,000 persons were actually being treated.
- The Guntur Centre was supposed to open on December 1, 2004. However, the salary offered for the doctor was considered inadequate, and the post remained vacant until the end of February 2005. Treatment was therefore delayed, even though drugs, CD4 machine, testing kits and the lab technicians were available.
- A representative of the Telugu Network of People Living with HIV/AIDS, said that in Andhra Pradesh, "*the functioning of the doctors in this regard is most unsatisfactory. Doctors have not been trained. The senior doctors may be trained, but it is the junior doctors who*

are attending to the rollout centres. Every rollout centre has an in-charge doctor. The in-charge gets trained, but it is not he, but the junior doctor, who attends to the centre. This junior doctor will have no understanding of side effects, drug resistance, where to get second line drugs, and so on. These doctors make no inquiry as to the medical history of the person, the symptoms, the treatment taken prior, if any, and so on. No information is given to the person. For example, the person must be told that the drug has to be taken regularly without any breaks. If this is done, the drug will be effective for a considerable period of time. If the drug is taken in an irregular fashion, the long-term efficacy of the drug is drastically reduced. This has consequences for the person in terms of drug resistance. They were not familiar with the NACO guidelines. The paediatric syrup is not made available. As a result, children are not being enrolled in any centre."

- In the first year of the Government's roll out, 1,000 PLHA were declared eligible for ARV treatment, but only 600 were enrolled. When asked why, the authorities replied that they kept the stock relating to 400 persons in reserve, because the drugs in the next year may come late and it was necessary not to have a break in the treatment for the 600 persons.
- All the centres, other than the one at Osmania, treat only people from the same district and the surrounding two districts. The authorities insist that all those outside these three districts must go to Osmania. There is a total of 23 districts in Andhra Pradesh. 14 districts are in the 1-2% prevalence range, 2 districts are below 1 % prevalence, and 7 districts are above 2% prevalence. As a result, there are long queues at all the treatment centres and people are put to great inconvenience.
- There is no family counselling provided at any of these centres, except in the Chest Hospital, which is run not by the Government, but by the Network. The doctors treat the patients with disrespect.
- The CD4 count test, as per the NACO guidelines, is to be done once every 6 months [depending on circumstances]. In Andhra Pradesh, after the first testing, follow-up CD4 tests have never been done.

Maharashtra

- According to SACS, there were approximately 10,00,000 HIV positive people in the state of Maharashtra. The number of such

persons requiring ART was approximately 1,500.[143] The State of Maharashtra has only one CD4 machine in the entire state. There are two other machines, but they are not functioning. Whereas other states do not charge for CD4 testing, and those that do charge only Rs 500, hospitals in Maharashtra charge Rs 800.

- According to a representative of the Udaan Trust, one of the hospitals caters to 1,500 persons, but the treatment is well below the recommended standard. The doctor generally sees 15 patients at a time in a group, conducts no individual examination, and prescribes the drug in a cursory manner. They sometimes use abusive language. Marginalised communities are stigmatised and made fun of. No inquiry is made of the patients as to the existence of any opportunistic infection, and the entire process is done in a mechanical fashion. The hospital maintains no data on adherence, drug resistance or death. The centres themselves are in a pathetic condition. There is no place to sit, there are no fans and clean drinking water is not available. Mr Vijay Nair further stated that people are called repeatedly for tests and the entire process may take up to 1½ months, with patients having to stand in line from 4am in the morning for CD4 testing. On average, a person has to visit the hospital four times to begin treatment. People come from all over Maharashtra to the J.J. Hospital for this purpose, travelling hundreds of kilometres and spending huge amounts of money. The entire process is traumatising and financially devastating.

Tamil Nadu

- In 2004/5, this state had approximately 5,00,000 HIV positive persons. The number of those requiring ART was approximately 60,000, with ART being provided at three hospitals at Chennai, and one hospital at Madurai. According to the Indian Network for People Living with HIV/AIDS, "*although the programme has been launched some time back, the public remains quite unaware of it. The doctors are not adequately trained. Those that are trained are generally senior, and do not attend to the PLWHAs. Junior doctors, and even house surgeons who are 5th year students, deal with the persons. There is no facility for nutrition or food. The ARV drug is*

143 This is probably the number registered at ART centres – the actual figure is very likely to be much higher

toxic and requires adequate nutrition. People below the poverty line are required to have a special diet. The state has made no attempt to ensure this. Their sensitivity and training leaves much to be desired."

- HIV positive persons who are not suffering from tuberculosis are often sent to the Tambaram Hospital, which is a specialist tuberculosis centre. Tuberculosis is one of the most prominent and contagious OIs. These PLHA therefore stand a high chance of contracting the disease there. There are no paediatric drugs available. The tablet is being broken and given to the baby. This is not advisable. There is no child care.
- It was further stated, "*Persons taking the ARV from private sources before the launch of the Government programme are not in a position to switch over to the public programme because on taking the ARV their viral load has increased. This is an irrational position and NACO ought to revise the guidelines to permit persons to switch from the private consumption of drugs to the Government system even with a CD4 count higher than 200.*"

Kerala

- The total number of HIV positive persons in this state was approximately 1,00,000, as per KSACS. The estimated number of people requiring ART was approximately 1,000. The state began implementing the free drug policy from November 2004. 800 people are today receiving the drugs through five Government medical colleges. There was only one Government-owned CD4 count machine in the entire state, and this is at the Trivandrum Medical College. In 2004, 3,000 persons approached this facility. An equal number approached the private sector.
- According to CPK+, "*the waiting list for the CD4 test was 1000 persons, which will occupy the machines until December 2005. Due to bureaucratic procedures, the machine is operated only 3 days a week with only 10 persons a day. There are three additional CD4 machines purchased after Network pressure, but these are not functioning.*"
- According to Anasuya Foundation for Integrated Research in Mental Health, "*there are no paediatric formulations. Drugs for OIs are not available. The costly ARV drugs for the second line treatment*

are generally not available. The following Nucleoside Reverse Transcriptase Inhibitors (NsRTIs) are in the WHO list of essential medicines, but are not available: Didanosine (ddI), Abacavir (ABC). The following Protease Inhibitors (PIs) are in the WHO 2002 list of essential medicines, but are not available: Saquinavir (SQV), Ritonavir (RTV), Indinavir (IDV), Nelfinavir (NFV), Lopinavir/ Ritonavir (LPV/r)."

- According to CPK+, each centre is over-burdened and serves 6 districts. People have to wait for days to be treated. In the out-patient department, 60-80 persons come every day, but there is only one doctor to tend to them. This doctor used to work every day earlier, but now works only 3 days a week. No proper drugs are available for a combination of tuberculosis and HIV, as a result of which, people are dying.
- There have been reports that one of the ARV drugs, Stavudine 30, is often not available, and therefore Stavudine 40 dose is given instead. This is extremely hazardous as the latter is meant only for people weighing more than 60kg.

Karnataka

- There were 5,00,000 HIV positive persons in this state. Approximately 10%, or 50,000 persons, need ARV. The ARV drugs are available at the Government centres at Hubli, Mysore, and Bangalore. ART started at the Bowring Hospital, Bangalore, on 1 April 2004. 700 persons are treated here. The Hubli Hospital treats 400 persons, and the Mysore Hospital treats 250. However, the CD4 count facilities are available only at Bangalore as of now. There are huge queues for testing. CD4 count reports done from private laboratories are not accepted by the Government. In the private sector, it costs between Rs 500-1000 to have a CD4 count test done.
- According to KNP+ "*there is only doctor at Bowring Hospital. He monitors 20-25 patients per day. They have to stay at the hospital for the whole day. People are often seen lying in the parking areas. There are no seating areas, and no toilet facilities. Patients ask, "What is the benefit of getting drugs free, if they have to pay an equivalent amount for travel to the hospital?" Free travel, including a railway pass, ought to be given, as provided for 40 categories of person under the railway rules, which include disabled persons and*

cancer sufferers and so on. Since the CD4 testing can be done only at Bangalore, persons incur huge expenses travelling to and fro. There is absolutely no reason why thereafter the drugs cannot be delivered at the districts, or even at the places of residence, instead of requiring the persons to repeatedly come every month to the main centres. Policy needs to be drastically changed in this regard. An outpatient treatment model is necessary which intervenes at an early stage, instead of picking up people at the last stage."

- In Karnataka, about 20% of the people receiving ARV drugs need second line drugs.
- In the Networks' experience, only people who are very sick and whose CD4 count is below 100 are getting treatment. In the absence of proper nutrition, it is doubtful if their lives can be affected by providing treatment at that stage. Many people have died after getting drugs at a late stage. There is no shortage of drugs, but the Government is unable to reach its target.
- The KNP+ representative further stated that, "*it is strange that the Government does not advertise anywhere in the country that free drugs are available for PLHAs at centres across the country. At the same time, Government complains that they are not able to meet their targets. The lack of information is deliberate. In the opinion of activists, were the public and PLWHAs made aware of the fact that free drugs are available, there would be a huge response and there would be manifold increase in testing. The Government is not willing to face the reality of the situation. It prefers to live in a dream world, where it pretends that the situation is not so grave. As a result, its conduct only exacerbates the situation. In Bagalkot District alone in 2004, 3000 new infections were reported. If this is true, the statement of the health minister that there are only 28,000 new infections in the entire country appears to be wilful misinformation.*"

Uttar Pradesh

- Approximately 5,00,000 HIV positive persons live in Uttar Pradesh, of whom about 50,000 need ART. As of August 2005, 480 persons were registered at the Sir Sunderlal Hospital at Benaras. Another centre is to be opened at the King George Medical Hospital, Lucknow, but this has not yet started.

- According to the Uttar Pradesh Welfare for People, Living with HIV AIDS Society (U.P. Network) "*there is a CD4 machine at Lucknow, but it is not being used. The CD4 machine at Benaras is dysfunctional. For blood tests and for tuberculosis tests, charges are levied. Counselling is done in a mechanical fashion. There is no one-to-one counselling. It is done in a crowded room, in a casual fashion, and restricted to basic details about how the drug ought to be taken. On the death of the bread-earner, the family and the children are left destitute. A rehabilitation scheme ought to be put in place.*"
- Right to information is a sore point for positive persons. The state does not even provide the most basic information relating either to the virus itself, the treatment, counselling or to social issues such as stigma and discrimination. As a result, doctors and patients and the families of affected persons remain in a great state of ignorance. The state ought to use the communications system at its disposal, namely television and radio, to aggressively spread the message about HIV/AIDS and treatment. In *PUCL* v *Union of India* [the starvation deaths case], the Supreme Court directed Government to regularly show on television and carry on the radio information and messages relating to the proceedings in the Supreme Court, the policies of the Government, and the orders of the court. Similar orders ought to be made regarding treatment of PLHA.

Rajasthan

- Rajasthan had about 3,00,000 HIV-positive persons. The number of people requiring ART was approximately 30,000. The state had identified only 5,000 persons to receive treatment from the Government. Out of that, only about 500 were actually getting the drugs. These drugs are only available through the Government at SMS Hospital, Jaipur.
- According to the representative from the Rajasthan Network for People Living with HIV/AIDS, "*there are no doctors for the dispensation of the drugs. The counsellors do the providing of the drugs. The doctor who was trained to treat the patients is now the project director. He entertains patients at his house, and charges them for that. He does not see any patients at the hospital. 1000 persons were started on the ART regime in 2001, and discontinued*

4 months later. Several persons died as a result thereof. I was one such person whose drugs were discontinued. I have seen his friends die. The ARV rollout has started in early August 2005."

- He further stated that, "*under GIPA* [Greater Involvement of PLHA], *the positive persons are to do peer counselling, along with the counsellors. Persons have been appointed and are now functioning as such, but they are not being paid wages. Instead, they are being paid Rs 50 honorarium. He or she has to travel to the counselling venue, and spend time there, only to suffer the indignity of not even being paid the minimum wage, which is approximately Rs 85 in Rajasthan. In the circumstances, the peer counselling system is likely to collapse. Millions of rupees are spent on fake awareness programs, but there is no awareness in society at all. An inquiry into how the funds are being spent may perhaps yield interesting results.*"

Manipur

- Manipur had 20,297 HIV positive persons as of June 2005. There were 3,446 cases of AIDS, and 492 people have died, according Manipur State AIDS Control Society.
- Drugs were available at 2 centres, namely the Regional Institute of Medical Sciences and the J.N. Hospital. At RIMS, there are 232 people getting drugs today, but the wait list is 1117 as of June 2005. The quota here is for 300 persons. In the J.N. Hospital, the quota is 200. Approximately 197 persons were being provided drugs, and the wait list is 500. From September, two more districts are planned for ARV rollout, Churachandpur and Ukhrul.
- Ironically, while there is a huge waiting list, ARV drugs are apparently available but are not being used and are about to expire. Inexplicably, persons are being told to buy drugs off the market, and that the Government will reimburse them.
- Free treatment started in April 2004. As a result of increased testing, 500 new HIV positive cases were registered in September and October 2004.
- According to AVAHAN Project, Manipur Network of Positive People, "*there is no paediatric dose of ARVs for children with HIV. GIPA guidelines are not being followed. tuberculosis medicines are likewise not available for children. The counselling rooms have no*

privacy. Trimune 30 is occasionally not available and the officials give Trimune 40 which is not to be done. This is powdered and a reduced dose is given. Drugs are being supplied in a very irregular fashion. If at all there is a shortage they ought to be airlifted as tuberculosis drugs are at times of shortages."

Himachal Pradesh

- According to the Himachal Pradesh Voluntary Health Association, *"1212 HIV positive cases have been detected. There are estimated 5,000 cases of positive people. The numbers are going up dramatically. There is no CD4 machine in the Government sector in HP and there are no ARV drugs available to the patients."*

Orissa

- According to a representative from the Drug De-addiction Center Project Swarajya, *"there are 2915 identified HIV positive cases in 30 districts. 467 persons have AIDS. 285 have died. Presently, there is no CD 4 count machine in the Government sector. ARV treatment is not available."*

Second National Consultation

The second National Consultation was held in October 2006 in New Delhi. The Consultation was called to discuss and include the demands of PLHA in the court proceedings of the *VHAP* v *Union of India* case, so that a collective consensus regarding the demands from the Government could be arrived at. The Consultation brought in 15 participants from 10 state networks.

Table 6 below demonstrates the true ground situation of the National ART programme in India in the year 2005-2006, as reported by various network representatives present at the consultation. Again, no **independent verification of this data has been carried out by HRLN,** although we believe the information to be broadly accurate.

Table 6

States	No. of Districts	No. of ART centres	No. of CD4 machines
Andhra Pradesh	23	3	3
Tamil Nadu	30	13	5
Rajasthan	32	2	2

States	No. of Districts	No. of ART centres	No. of CD4 machines
Orissa	30	NIL	NIL
Himachal Pradesh	12	1	NIL
Goa	2	1	1
Delhi	-	5	3
West Bengal	18	2	1
Punjab and Haryana	20	3	3
Nagaland	8	4	1
Madhya Pradesh	50	2	1

It is apparent from the chart above that most of the States had inadequate ART centres and CD4 machines. For instance, in the whole State of Orissa there was no ART centre or CD4 machine. The delegates also highlighted some of the specific problems relating to ART treatment in their respective States:

Andhra Pradesh

- 11 ART centres had been sanctioned by the Government, but only 3 centres were functional, and ART was not available for marginalised communities. 5,000 HIV positive persons had been identified. People travel long distances to get to roll out centres, and while they are being tested, several days are required. They spend a huge amount of money in travel fare, accommodation and food.

Goa

- 11,000 HIV positive people had been identified, of which 1,285 people have been registered and 391 were receiving ART. One of the positive networks reported that cases were increasing due to lack of follow up. The Goa Medical College is a very crowded place, and healthcare providers show stigma towards PLHA. Doctors are not giving specific instructions on how to follow up cases.
- People cannot get tested unless they have an identity card. Even where kits are available, testing is sometimes refused because the daily quota set by the hospital has been met.

Tamil Nadu

- There were 13 ART centres functional in 2006. However, 62,000 positive people need ART in the state when only 13,000 people are

getting ART. The State networks reported that people who were obtaining ART privately had become very poor, and needed to shift over to public ART.

- There are five CD4 count machines in the state, of which two are dysfunctional. The Network reported that the quality of testing is also very poor. For instance, when a blood sample is sent to two different centres, two different results are reported. There is therefore need for standardisation.

Delhi

- There were six functional ART centres in Delhi. In 2004, 42,000 people were identified as requiring treatment, but only 3,650 were actually receiving it. 100 people need second line ART. In 2006, 7,323 persons were registered as receiving treatment and 645 people had discontinued treatment.
- According to NACO, money is available for treatment for 1,50,000 people, but the people are not coming forward. The Networks complained about the lack of publicity for the national ART rollout programme. In Lala Ram Swarup tuberculosis Hospital, RML Hospital and AIIMS, there were breaks in supply of the ARV drugs. In December 2005, EFV and M Tri 40 mg were not available for more than one month. In RML in July 2006, EFV was not available for more than 7 days.
- There are 5 CD4 count machines in Delhi. In Safdarjung and NICD, they charge Rs. 500 per test. In AIIMS, the first test costs Rs. 800 and thereafter, the tests are free. If the referral is from any other doctor, the charge is Rs. 800 per test. In RML the waiting period is between 1-2 months.

Madhya Pradesh

- There are 2 ART centres that were functional. It was reported that out of 25,000 HIV positive people, only 940 persons were receiving ART. Out of 940 people requiring second line ARV drugs, only 40 people are receiving second line treatment.
- For 20 days in April 2006, there was a break in supply, as a result of which many people became sick, and many required second line treatment, due to developing resistance through non-adherence.
- The Networks reported there is only one CD4 count machine in a private hospital, and none in the rollout centres. Rs. 500 is charged

per test. The doctor operating this machine routinely tells people that the machine is not reliable, and refers them to a private machine which charges Rs. 1500 per test.

Himachal Pradesh

- There is only 1 ART centre in the state and, out of 4000 positive people, only 500 are getting the requisite treatment.
- There is one CD4 count machine in a public hospital, but people are told that the kits are unavailable to do the test. Patients are told they have to send the blood to Hyderabad in Andhra Pradesh for testing in a private CD4 count machine, at a cost of Rs 185.

West Bengal

- There are 2 functional ART centres. Although there were 11,800 positive people identified, currently the number of PLHA stands at about 20,000. There are 801 male, 233 females, 32 children receiving ART in 2006. Due to lack of follow up, many people have discontinued their treatment, and some have died. Many people are not traceable.
- There are gaps in procurement and supply. There is a lot of confusion because the colour, size, box size, quantity and combination changes from time to time.
- 100 people are in need of second line treatment.
- There is only one CD4 count machine in the entire State. People from North Bengal have to travel for 2 days to reach the CD4 machine in the Tropical Medical College, West Bengal.

Rajasthan

- There are two functional ART centres. Out of 63,000 positive people, only 700 people are getting ART, and an additional 600 people urgently need ART. There are 1,200 people receiving private ART. 90 people urgently need second line.
- The drop out rate is very high, particularly amongst widows.
- CD4 kits are invariably out of stock. The Government purchased the CD4 machines with older technology. Now the Government has purchased a newer machine and newer kits are available, but the Government is trying to use the new kits on the old machines. For these CD4 count machines, both old and new, the company providing the machines does not have service centres, and does not have back up services.

Haryana and Punjab

- There are four ART centres in both States combined. The Networks reported that 6,000 positive people are in need of treatment, whereas only 2,000 have been registered and only 300 were receiving treatment. PLHA are having to pay before they get admitted to the public hospitals – if they don't pay Rs. 1,000, they are not even admitted.

Nagaland

- There are four ART centres in Nagaland. There are 274 adults and 13 children receiving ART.
- CD4 count testing is available only on Tuesday and Thursday, which is inconvenient to PLHA who have to make difficult journeys to reach the CD4 count machines.

Orissa

- There is no ART centre in Orissa. 3,961 positive people were identified, and people have to travel to neighbouring states such as West Bengal, Bihar and Andhra Pradesh for treatment. Travel costs and time spent is therefore high.
- Testing is done only in private hospitals where Rs. 1,200 – 1,500 is charged.

Third National Consultation

The third national consultation was held in September 2007 in New Delhi.

Table 7 below demonstrates the situation of the national ART programme in India in the year 2006-2007, as reported by the representatives of the positive networks present at the consultation. Again, no independent verification of this data has been carried out by HRLN, although we believe the information to be broadly accurate.

Table 7

STATES	No. of Districts	No. of ART centres	No. of CD4 machines
Andhra Pradesh	23	5	7
Goa	2	1	1
Tamil Nadu	30	19	6

STATES	No. of Districts	No. of ART centres	No. of CD4 machines
Delhi	-	8	5
West Bengal	18	3	1
Himachal Pradesh	12	1	1
Rajasthan	32	2	2
Punjab and Haryana	20+20	4	2
Orissa	30	1	NIL
Nagaland	8	3	3
Madhya Pradesh	50	2	1
Bihar	38	2	2
Manipur	9	5	4
Karnataka	29	15	4
Kerala	14	5	4
Maharashtra	37	18	7

Delhi

- There were 5 CD4 machines, the use of which did not incur a charge.
- 10,960 people were registered for ARV treatment, yet only 5,000 have commenced such treatment. There are 2,050 people on private ARV treatment. 1,670 people had discontinued due to a lack of follow-up, of which 1,558 were adults and 112 were children.
- Many CD4 count tests are conducted in Delhi for people coming from other states .

Tamil Nadu

- There are 19 ART centres and 6 CD4 machines in the state, all of which are functioning. Five more are expected.
- Paediatric ART has started in all centres. About 1,200 children are already being treated.
- The problem of lack of standardisation of different ART centres persists however. Blood samples sent to two centres give two different sets of results.

Goa

- There is one ART centre in Goa, in the Medical College, and 1 CD4 count machine which has not been working for the past 2-5

months. Travelling to the one ART centre from South Goa to North Goa is expensive.

- Testing is sometimes refused, despite availability of kits, in order to meet the daily quotas set by the Government.

West Bengal

- There are 18 districts in West Bengal, with only 3 ART centres (in the School of Tropical Medicine, AGM and NB Medical College).
- 1,800 people receive ART treatment, and there is a drop out rate of approximately 50%. There are also transportation problems, in that North Bengal residents are required to travel for 2 days to get to the centre. More machines are urgently required.

Madhya Pradesh

- The state has only two ART centres, one in Bhopal and one in Indore, and only one CD4 machine. Madhya Pradesh is a big state, with poor resources.
- In April 2006, there was a break in supply of the drugs for 20 days. As a result, many people became ill.
- People from public hospitals are often referred to private hospitals for testing, which costs them Rs. 15,000

Himachal Pradesh

- There is only one ART centre and one CD4 count machine, in Shimla. One centre for 12 districts is not enough, and does not allow access for everyone.

Rajasthan

- There are 33 districts, and only two ART centres with two CD4 count machines, in Jaipur and Jodhpur.
- There are 650 dropouts, out of 3,000 people receiving ART treatment. There are 500 people receiving private treatment and CD4 kits are invariably out of stock.

Punjab and Haryana

- There are 20 districts in Punjab, but only two ART centres, in Amritsar and Jalandhar. There is only one CD4 count machine, in Amritsar. Samples taken in Jalandhar are sent to Amritsar.

- Haryana also has 20 districts, and only one CD4 machine in Rohtak. All of Haryana has to come to Chandigarh for treatment.
- At the Chandigarh ART centre, 165 patients who have taken ART treatment died, out of the 3000 registered. 10 patients are in need of second line treatment, out of which only 6 are receiving and 4 are waiting for treatment due to lack of funds.

Bihar

- There are two centres and two CD4 count machines, in Patna and Muzzarafpur, for 36 districts.
- When there are floods, and it is so difficult to move around the state, PLHA on ART should be given ART supply for two months, rather than the normal one month.
- Each centre has 2500 persons registered. PLHA have to travel from long distances to get to an ART centre, and poor are unable to afford it.
- Out of 50 PLHA who require second line treatment, only 10 are receiving it.
- In the centres themselves, there are no seating arrangements.

Manipur

- There are five centres and four CD4 count machines. More than 3912 persons have access to ART. Figures up to September 2006 are that 4577 people are registered for ART, and there are 84 dropouts.

Karnataka

- There are 15 ART centres and four CD4 machines, in Bangalore, Mysore, Hubli and Gulbarga. The CD4 machine in Gulbarga is not working.

Orissa

- There are 30 districts in Orissa, but only one ART centre, in Ganjam District. There is no CD 4 count machine in Orissa.
- There were 7600 positive people identified as in need of ART, but only 300 were receiving ART treatment. Orissa SACS report says that 93 children need ART treatment. Due to the long queues for taking blood samples, these are sent to West Bengal.

Nagaland

- There are three ART centres, but the centre at Dimapur is not functioning. There are three CD4 count machines, of which only two are working.

- There are only 13 children on ART and paediatric drugs are generally unavailable.
- The long distances which people are required to travel to access treatment are a problem.

Uttar Pradesh

- There are 70 districts in Uttar Pradesh, but only three ART centres. The CD4 count machine in Lucknow has been dysfunctional for the last 13 months. There are no trained doctors, and the only doctors that are available work just 4-5 hours per day.
- There is no drinking water available in the centres.

Kerala

- There are five ART centres, and four CD4 count machines, but the one at Trissur is not functioning.
- More than 4780 people are registered for ART, 86 people died in 2007, and there are 218 drop outs. 250 children receive ART, 2900 adults take ART treatment and most other people in need are obtaining treatment from the private sector.

Maharashtra

- There are 18 ART centres, seven CD4 count machines, four treatment and counselling centres and there is one Positive Living Centre in Pune. 11749 people are registered at the ART centres, 4461 positive persons are receiving ART treatment. 350 children urgently need treatment, and the treatment has not been made available.
- There is lack of confidentiality in the Government Medical Colleges. 200 people are coming per day, but there is only one counsellor available. PLHA from Madhya Pradesh and Chattisgarh all have to come to Nagpur for treatment.

Andhra Pradesh

- There are five ART centres and seven CD4 count machines in Andhra Pradesh. 13300 people are registered at the ART centres, and 3700 are receiving ART, of which there is a 10% dropout rate. 120 children are receiving paediatric ART. The second line treatment is unavailable.
- CD4 tests are not done for all people, because doctors only prescribe tests when the opportunistic infections become serious.

Fourth National Consultation

The fourth National Consultation was held in March, 2008 in Delhi. Table 8 below demonstrates the situation of the national ART programme in India in the year 2007-2008, as reported by the representatives of the positive networks. **Again, no independent verification of this data has** been carried out by HRLN, although we believe the information to be broadly accurate.

Table 8

States	No. of Districts	No. of ART centres	No. of CD4 machines
Andhra Pradesh	23	19	6
Goa	2	1	1
Tamil Nadu	30	19	6
Delhi	-	9	5
West Bengal	18	4	2
Himachal Pradesh	12	1	1
Rajasthan	32	4	4
Punjab and Haryana	20+20	4	4
Orissa	30	1	1
Nagaland	8	3	3
Madhya Pradesh	50	2	1
Bihar	38	2	2
Manipur	9	5	4
Karnataka	29	16	6
Kerala	14	5	4
Maharashtra	37	26	12
Uttar Pradesh	70	6	3
Gujarat	25	3	1
Nagaland	8	3	3
Meghalaya	1	1	1

The fourth National consultation was held after the Supreme Court hearing of the VHAP case in February 2008. Though the numbers of ART centres have increased in certain states compared to earlier years, the condition remains abysmal.

Delhi

- 60,000 PLHA are registered at the ART centres. People from Uttar Pradesh, Haryana, Bihar, Leh and Rajasthan are coming to Delhi for treatment. About 200 PLHA are obtaining second line treatment from the private sector.
- The new CD4 count machine installed GTB Hospital is not working. Viral load tests are done privately at Ranbaxy and Dr. Lal's Path Lab – this costs Rs 4,000-5,000.
- Drugs for opportunistic infections such as septron, becosule, antibiotics and multi vitamins, cyclovir, metrogyl, etc . are not available.

Goa

- 10-12000 people are HIV positive, according to SACS . Only 600 PLHA are registered for ART, out of which only 520 are getting ARV drugs.
- The only CD4 count machine available in the State breaks down every 2-3 months.
- One of the state positive networks reported that at the ART centres, the doctors arrive late, and that there are no chairs or drinking water. Approximately 150 people have dropped out from the ART centres. The doctors write a person's HIV status on their case papers, and OI drugs are not available.

West Bengal

- 1,800 people are receiving ART. Patients are subjected to lengthy waits for medicines at the ART centres, and there is no drinking water available.
- Travel issues persist. For many it is between a 3 hours and overnight journey to get to the ART Centres. Blood samples are collected by the district networks and sent to the closest machine for testing.
- Drugs for opportunistic infections are not available. Hospitals are collecting money from people for drugs. Hospitals claim they are unable to meet the demands of the people and no counsellors have been placed at the centres.

Rajasthan

- 1,900 people need ART urgently, whereas only 700 are being provided with it. 500 are receiving private treatment, and there is a drop out rate of 650, from a total of 3,000.

- Peer counsellors' salaries are paid by NGOs through the positive networks, not by RSACS.
- No routine tests are done before starting ART, and there are no paediatricians at the ART centres.

Bihar

- 16,000 people are registered as HIV positive in the State. 4,000 are registered for ART, of which only 1,906 are receiving ART. Between 40 and 50 people are receiving second line treatment from the private sector. 127 people have dropped out from the ART centres.
- Poor people are unable to travel to the centres from other districts due to the cost of travel. Each time someone travels to receive treatment, it costs them about Rs. 600-700 in travel costs and food.
- Paediatric syrups are unavailable for children.

Manipur

- Facilities in the ART centres are very poor – seating, drinking facilities and toilets are unavailable and there are breaks in the drug supply.

Orissa

- There are 30 districts in Orissa, and only one CD4 count machine. 8,502 PLHA have been identified as HIV positive, out of which 2,187 PLHA have registered with the ART centres, but only 838 are on treatment. 50 people have dropped out.
- Pre- and post-test counselling is not done properly.
- In public hospitals, patients are asked to purchase drugs privately.
- The state Government has announced a pension of only Rs. 200 per month per person.

Maharashtra

- Since June 2007, there have been 26 centres open, and the total number of people registered for ART is 11,749. 350 children in Pune require treatment, but have not yet started ART.
- People from Madhya Pradesh, Chattisgarh and Andhra Pradesh are using the Nagpur ART centre for treatment, but there are no proper seating arrangements and the conditions are not hygienic.

Madhya Pradesh

- In April 2006, there was a break in supply of ARV drugs for 20 days. Consequently, many people became ill.
- People from public hospitals are referred to private hospitals for the tests, which can cost them as much as Rs. 15,000/-.

Himachal Pradesh

- There are 12 districts in this hilly state, but there is still only one centre, which is not accessible. There is a lack of infrastructure.
- 477 people are registered on ART.

Kerala

- There are 60,000 PLHA in Kerala. 7,908 are registered with ART centres, and 3,402 are receiving ART. There are 388 children registered for ARV, and 172 are getting paediatric drugs.
- 88 people need second line treatment. There are 20 people on private ART.
- The CD4 count machine in Trissur is still dysfunctional.

Uttar Pradesh

- The Gorakhpur ART centre has no doctor, and the medicines are being prescribed by staff nurses, not doctors.
- Treatment for opportunistic infections is not available anywhere in the State.
- To get tests done, people are asked to purchase gloves and syringes from outside the hospital, which they then have to pay for.
- There are 70 Voluntary Counselling and Testing Centres ("VCTC"). There used to be 140 counsellors, but now only 70 are available. In many centres there are counsellors of only one gender, adversely affecting the other gender that comes in for counselling. In nine medical colleges, there were peer counsellors, but they were all removed without reason in Oct 2007.

Andhra Pradesh

- 3,20,000 PLHA are registered at the VCTC in the State and 26,000 people are receiving ART. There are 1,200 instances of drop outs.

3,000 people are receiving ART from the private sector, and 50 are on second line treatment.

- There is an irregular supply of drugs in Guntur and Prakasm District. There are also reports of 15 day drug cycles for people on treatment, due to shortage of supply.
- In November 2007, there were also shortages of CD4 kits and testing kits.

Gujarat

- 5,000 PLHA have been registered by the networks. 1,102 people are receiving ARV drugs.
- The CD4 count tests yield different results depending on which machine is used. As a result, many people wrongly started taking ARV drugs.
- A shortage of drugs has been reported.

Nagaland

- Only 13 children are on ART, and paediatric drugs are generally unavailable.
- Only two CD4 count machines are working – the one at Dimapur is not working.

Karnataka

- Second line treatment is not available due to which a lot of people are dying on a weekly basis.

Punjab and Haryana

- Officially, there are 16,800 positive people living in Punjab and 20,000 in Haryana, of which 5,000 live in Chandigarh. The unofficial figures are, however, four times higher.
- The numbers of people registered for ART are as follows – Punjab 3,065, Chandigarh 3,925. 1,225 PLHA are receiving treatment in Punjab and 1,915 are receiving treatment in Chandigarh. In 2007, there were 166 cases of people dropping out.
- Medicines for opportunistic infections and multi-vitamins are not available in the required quantities.

Tamil Nadu

- People receiving private ART have become poor, and need to shift into the public system.
- 1,200 children are on paediatric ART.
- The issue of standardisation of the testing centres continues.

Fifth National Consultation

The purpose of the fifth National Consultation, which was held in New Delhi in August 2008, was slightly different from the previous four consultations. The purpose this time was to discuss the points put forward by NACO in the *VHAP* case, their practicality, implementation and monitoring. There was a particular focus in the discussion on second line treatment and the Government's refusal to set any hard targets for a roll out of second line treatment.

A full explanation of the *VHAP* case, its development and impact can be found in Chapter 5.

It is clear form the above mentioned data from 2004-2008, that the state of the national ART programme has been dreadful. PLHA continue to die due to lack of drugs and infrastructure. In a moderate-prevalence state such as Orissa, there is one CD4 count machine available for the 30 districts, and this has been dysfunctional for long periods, and people have been routinely dying as a result. In a state such as Manipur, which is not only the highest prevalence state in the country, but is also under the Armed Forces Special Powers Act, PLHA have to go without drugs for months due, in part, to the political instability. Uttar Pradesh is the largest State in the country with 70 districts, and two CD4 count machines out of three were dysfunctional for months. The doctors and health care workers are under-trained everywhere, and insensitive in just about every ART centre in the country. A lack of nutrition and proper travel facilities have resulted in lots of avoidable deaths.

It is time that the Government woke up to the needs of PLHA in India and reformed the national ARV programme. It would be prudent for India to draw from the experience and best practices of other developing countries such as Brazil. The ART experience in other countries is discussed in detail in the next chapter.

CHAPTER 7

ART experience from abroad

The Struggle to Attain Access to Affordable Antiretroviral Treatment in South Africa

Despite being a Government rhetorically committed to transformation, in the context of the post-apartheid era, progression in the provision of HIV/AIDS treatment could not be so categorised. In fact, it has been regressive in nature.[144] The initial obstacle presenting itself in South Africa was the lack of a constant supply of affordable antiretroviral drugs. Although pressure at a local and international level had a significant impact, the Treatment Action Campaign ("TAC") held the view that the cost of the necessary drugs would only drop to affordable levels with the onset of generic competition.[145]

In tackling the AIDS epidemic, the situation in South Africa can best be viewed as a constant struggle. Recent years have seen positive progressive steps taken by the South African Constitutional Court, but this has conflicted sharply with the bewildering stance of the political leadership.[146] For example, former President Mbeki and the former Minister for Health questioned the positive effect of AZT in preventing the transmission of HIV from mother to child.[147] It is hoped that with the

144 Forman, Lisa, '*Ensuring Reasonable Health: Health Rights, The Judiciary, and South Africa HIV/AIDS Policy*' (2005) 33 Journal of Law, Medicine and Ethics 711, at 713

145 Treatment Action Campaign was launched on 10 December 1989, International Human Rights Day, with the primary intention of campaigning for the development and adoption of a comprehensive national treatment plan for people living with HIV/AIDS

146 See, for background, article accessed on 9 October 2008: h ttp://news.bbc.co.uk/1/hi/world/africa/720995.stm regarding the stance of South Africa's former President Thabo Mbeki in questioning the existence of AIDS and the impact of HIV on the body's immune system

147 Cauvin, Henri E., 'South Africa Retreats from AIDS Debate', *N.Y. Times*, Oct 17, 2000 at A14

change in 2008 of political leadership, further progress can now be made in South Africa in the people's fight for universal access to treatment and removal of stigma and discrimination.

In 2003, the World Bank estimated that the average per capita gross national income in South Africa was US$2,780. This translates to a buying power of INT$10,270. With the expense of antiretroviral drugs capable of exceeding US$10,000 per patient per year, the limited access to the necessary medication was all too obvious.[148]

The multi-national pharmaceutical companies argue that access to the relevant medication has not been restricted as a result of the implementation of patent laws in South Africa. There may be some truth in this, but the point is that it is patent laws in other parts of the world that are the ultimate decider in availability and accessibility. Given that the vast majority of drugs are patented in Europe and the United States, drug manufacturers in these countries determine the cost of medication, regardless of the patent system in South Africa.[149]

With the TRIPS agreement[150] taking effect on January 1 1995, access to ARV treatment was to be complicated by yet another obstacle. Developing countries such as South Africa were given until 2000 to comply with the outlined patent protection. South Africa accepted the content of TRIPS, and inserted compliance with its provisions into the domestic law in 1997.[151]

Article 31 of the TRIPS agreement provides for compulsory licensing subject to certain conditions, including having attempted to negotiate with the patent-holder of the drug in question. This requirement is however waived where there is a "*national emergency, or other circumstances of extreme urgency or in cases of non-commercial public use*".[152]

148 World Bank, 2004. *World Development Indicators Database-South Africa*, available at http://devdata.worldbank.org/dataonline. This information is founded on purchasing power parity of international dollars which are described as possessing the same purchasing power over gross national income as the purchasing power of US$1 within the United States.

149 Halbert, Deborah, 'Moralised Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs' (2002) 1 *Seattle Journal of Social Justice* 257, at 268

150 Agreement on Trade Related Aspects of Intellectual Property Rights, administered by the World Trade Organisation

151 Intellectual Property Laws Amendment Act 38 of 1997 (South Africa)

152 Article 31(b) of the TRIPS Agreement

The South African Medicines and Related Substances Control Amendment Act 1997 included controversial provisions relating to compulsory licensing of drugs. This piece of legislation, amending the Medicines and Related Substances Control Amendment Act of 1965, took effect from May 2003 and set out certain conditions, upon satisfaction of which, the Minister of Health could proceed with registration of certain drugs, notwithstanding the fact the patent was held by someone else.[153] One of the provisions set out that, notwithstanding anything to the contrary contained in the Patents Act 1978, the Minister could determine that the rights associated with a medicine under a patent granted in South Africa shall not extend to acts in respect of such medicine where it has been put onto the market by the owner of the medicine, or with his or her consent.[154] It was also provided that in the event a medicine is identical in composition, meets the same quality standards and is intended to have the same proprietary name as that of another medicine already registered in South Africa, "*but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.*"[155]

The response from interested parties to this piece of legislation was vociferous, with much criticism coming from the Government of the United States and the large pharmaceutical companies, directed at the South African Government. In fact, the American Government initially threatened the South African Government with economic sanctions if it did not withdraw the amendment.[156] The problem from the perspective of the pharmaceutical companies was that new provision 15C "*could be used to justify and sanction both parallel importation and compulsory*

153 Section 15C (as amended)

154 Section 15C (a) (as amended)

155 Section 15C (b) (as amended)

156 Nash, Duane, 2000. 'South Africa's Medicines and Related Substance Control Amendment of 1997, 15 Berkeley Tech. Law Journal 485, at 486-487. However, the United States did remove this threat when the Government of South Africa asserted the validity of the provision under law, alleging that the United States was merely exerting pressure on behalf of domestic pharmaceutical interests

licensing of certain medicines", thereby circumventing protections contained in the TRIPS Agreement for patent holders.[157]

In February 1998, the Pharmaceutical Manufacturers Association and 42 pharmaceutical companies filed suit against the South African government on the ground that the new section 15C violated the South African Patents Act, and the obligations under the TRIPS Agreement. In April 2001, the PMA withdrew its suit, deciding to settle out of court. This settlement came about a month after the Treatment Action Campaign had entered the debate on the side of the Government.[158] Litigation has played a substantial role in advancing the cause of positive persons seeking treatment. In becoming involved in the *Pharmaceutical Manufacturers Association of South Africa and others v. The President of the Republic of South Africa and others*,[159] the objective of the Treatment Action Campaign was not just to concentrate on the relevant legislation, but to influence public opinion.[160]

In 2000, Boehringer Ingelheim, the manufacturer of Nevirapine, entered into an agreement with the United Nations to provide Nevirapine free of cost to developing countries for five years. However, even after Nevirapine was registered by South Africa's Medicines Control Council, the Government would only provide the drug at two pilot sites in each of the eleven provinces. Distribution of the drug was prohibited outside of these sites, even though approval for the drug had already been received from South African Authorities. Of particular concern was the fact that only 10% of the estimated 70,000 affected births would

157 Cleary, Susan, and Don Ross, 'The 1998 Legal Struggle between the South African Government and the International Pharmaceutical Industry: A Game-Theory Analysis', (2002) 27 *Journal of Social, Political and Economic Studies* 445, at 451

158 Block, Robert, and Gardiner Harris, 2001. 'Drug Makers Agree to Drop South African Suit--Bad PR Over AIDS Quells Efforts to Defend Patents; Pretoria Concedes Little', *Wall Street Journal*, April 19, at A12

159 *The Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*, 4183/98, High Court of South Africa (Transvaal Provincial Division) (March 2001), unreported case available at http://www.tac.org.za/Documents/MedicineActCourtCase/affiavd.doc

160 Heywood, Mark, 2001. 'Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation', *Paper presented at Health, Law and Human Rights: Exploring the Connections-An International Cross-Disciplinary Conference Honouring Jonathan M. Mann*, Philadelphia, Sept. 29 - Oct. 1, 2001. Indeed, the TAC's founding affidavit was deposed by the campaigns co-ordinator of South Africa's second largest trade union federation, the Congress of South African Trade Unions (COSATU).

be included within the scheme.[161] Without the required treatment, the mother-to-child transmission rate is 15-30 percent. With just a single dose of Nevirapine, however, transmissions during pregnancy, labour and delivery can be reduced by 50 per cent.[162] An investigation conducted by the National Institutes of Health in 1999 demonstrated the significant effect of Nevirapine[163] and, in August 2001, the Treatment Action Campaign filed suit against the Minister of Health in the Pretoria High Court.[164]

TAC argued that the scheme as implemented by the South African Government violated the content of the constitution to "*respect, protect, promote and fulfil the rights in the Bill of Rights*".[165] TAC sought directions that the Government should be forced to withdraw from its position of an outright prohibition against the distribution of Nevirapine outside of the pilot sites, and to create a more specific programme for the avoidance of such transmission. In resolving this issue, the Constitutional Court of South Africa, in what can be described as a groundbreaking judgment, agreed to both requests. In a unanimous opinion, the court was unable to establish any justification for the ninety percent of the affected pregnant women and children that were excluded from the programme. The Court held that the policy of the Government constituted a breach of the State's obligations under [Section] 27(2) read with [Section] 27(1) (a) of the Constitution.[166]

Further to this, the Court held that the Government was "*constitutionally obliged . . . to plan and implement an effective, comprehensive and progressive programme for the prevention of mother-to-child transmission of HIV throughout the country.*"[167] Nevertheless not all of the judgment handed down dispensed such glowing directions. There was a rejection of an insistence on the need for ongoing judicial

161 *Minister of Health v Treatment Action Campaign* (No. 2) 2002 (5) SA 721 (CC) (S. Afr.), paras. 10 – 12

162 http://www.avert.org/motherchild.htm, at notes 6 an d 7

163 Heywood, Mark, 'Current Developments: Preventing Mother-to-Child HIV Transmission in South Africa: Background, Strategies and Outcomes of the Treatment Action Campaign Against the Minister of Health' (2003) 19 *South African Journal of Human Rights* 278, at 285

164 *Minister of Health v Treatment Action Campaign* (No. 2) 2002, (5) SA 721 (CC) (S. Afr.), at 728

165 *South African Constitution*, 1996, chapter 2, section 7

166 Note 165, *supra*, at paragraph 80

167 Ibid., para. 5

supervision of the Government's HIV programs and unwillingness to carry forward an order of a lower court for the state provision of infant formula to poor mothers.[168]

In November 2003, the South African Department of Health circulated the Operational Plan to roll out HAART, with the intention of having 54,000 people receiving treatment by March 2004, increasing to around half a million in 2006, and onwards to a million in 2008.[169] The Department did not however release any ARV treatment guidelines until September 2004, and the slow pace of the roll out was alarming.[170] When funding from the Global Fund To Fight AIDS, Tuberculosis and Malaria and the United States President's Emergency Plan for AIDS Relief (PEPFAR) was made available from 2005, the pace of the public sector roll-out increased somewhat.[171] Although the number of patients receiving HAART increased from around 7,000 in mid-2004 to over 2,00,000 by September 2006, the number of people being treated was still only about 35 per cent of the target under the Ministry's Operational Plan.[172] The Operational Plan included plans for additional personnel, and there followed a considerable increase in the number of medical practitioners, professional nurses and pharmacists in the public system between 2003 and 2005.[173] Nevertheless, in general, the shortage of nursing staff posed a serious threat to further expansion of the access to treatment programme.[174]

168 Ibid., para. 48

169 Department of Health, 2003. *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa*, 19 November, available at http://www.hst.org.za/uploads/files/aidsplan.pdf

170 Department of Health, 2004. *National Treatment Guidelines*, available at http://www.doh.gov.za/docs/hivaids-progressrep.html

171 Nattrass, Nicoli, *Mortal Combat: AIDS Denialism and the Struggle for Antiretrovirals in South Africa*, Scottsville, South Africa: University of KwaZulu-Natal Press, 2007, p. 133

172 Hassan, F., and D. Bosch, *Monitoring the Provision of ARVs in South Africa: A Critical Assessment*. AIDS Law Project Briefing for the Treatment Action Campaign, NEC, 17 and 18 January, Cape Town. AIDS Law Project, Centre for Applied Legal Studies, University of Witwatersrand, 2006

173 In employment within the public health sector, the number of medical professionals increased by 1,101, the professional nurses by 2,096 and the number of pharmacists by 395, available at http://www.aids2006.org/Web/THLB0403.ppt_61,8,Slide 8

174 Note 172, *supra*, p. 136

Section 27 of the 1996 South African Constitution reads as follows:

"(1) Everyone has the right to have access to:

(a) health care services, including reproductive health care;

(b) sufficient food and water; and

(c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3) No one may be refused emergency medical treatment."

The Constitution Court interpreted this Section as placing a burden on the state to utilise its available resources to provide for measures necessary to ensure access to ARV drugs for those most in need. The Court recognised that it was not within the scope of its review to investigate the manner in which the necessary goals were intended to be achieved but the court's review of the Government's Operational Plan in the *Treatment Action Campaign* case shows that mere assertion of the existence of a plan will not be enough to show compliance with the provisions of Section 27.[175]

In January 2002, in announcing the intention of the provincial Government of KwaZulu-Natal to supply anti-retroviral drugs to pregnant mothers, Premier Mtashi questioned the fact that *"[a]s a Premier who heads a legitimate Government, I must ask myself, as our posterity will undoubtedly do, what went wrong in South Africa for a judge to have to order us to have a plan and re-prioritise in order to save our children,"* admitting that *"[c]ertainly, history will judge us harshly ..."*.[176]

Aspiring to the Brazilian Model

"If we can get cold coca cola and beer to every remote corner of Africa, it should not be impossible to do the same with drugs"

– Mr Joep Lange, founder of PharmAccess Foundation

175 *Government of the Republic of South Africa v. Grootboom*, 2001 (1) SA 46 (CC), para. 41

176 Premier Mtshali, *State of the Province Address*, February 25, 2002, extract available at http://www.afrol.com/Countries/South_Africa/documents/mtshali_aids_2002.htm

In trying to achieve this, the experience of Brazil cannot be overlooked.[177] Brazil can be viewed as an example for other economically-similar states. The number of individuals receiving ARV treatment stands at 100% of registered AIDS cases, and represents 20% of the estimated number of PLHA.[178] Brazil's estimated HIV/AIDS prevalence – 0.7% - is comparable to that of India which is estimated to be 0.36%, although there are variances between districts and states.[179]

Universal access in Brazil has relied not only on the patented drugs but on the generic version produced within the country by publicly owned companies. According to certain estimates, the cost of the required antiretroviral treatment would increase by as much as 32% were it to depend solely on patented imports.[180] By constantly threatening use of the 'national emergency' clause provided for under the TRIPS Agreement, and through repeatedly threatening parallel importing as a likely occurrence, Brazil has effectively and consistently managed to control the costs of antiretroviral drugs. Evidence of such successful manoeuvring is that the average individual cost per day of ARV between 1997 and 2000 reportedly decreased by 37%.[181] The fact remains that accessibility to the necessary drugs has had hugely positive effects, with AIDS-related mortality for the period to 2003 decreasing by as much as 50%.[182]

While the model constructed by Brazil is not easily replicated in countries such as India, the example offers inspiration for establishing appropriate life-saving solutions.[183] Brazil has an up-to-date system in

177 Lange, J., *Transcript of the Closing Ceremony of the XIV International AIDS Conference*, 2002, available at http://www.kaisernetwork.org/aids2002/transcript/transcript_webcast_12_a.html

178 Brazilian Ministry of Health, *Brazilian STD/AIDS Policy*, National STD/AIDS Programme, 2003. The latter figure is extracted from the estimate of 600,000 positive persons.

179 UNAIDS, Epidemic Update

180 Oliveira-Cruz, V., Kowalski, J., and McPake B., 'The Brazilian HIV-AIDS 'success story' – can others do it?' (2004) 9 *Tropical Medicine and International Health* 292, at 295.

181 Szwarcwald, C.L., *The impact of national production of ARV drugs on the cost of the ARV therapy in Brazil, 1997–2000*, Paper Presented at the XIV International AIDS Conference, 2002.

182 Note 79, *supra*

183 Medecins San Frontieres (MSF), 8,000 deaths a day, *Washington Post* [editorial], March 26, 2004, at A22

operation, offering treatment free of charge in the public health system. Brazil's position has not been without problems however. In 2001, Brazil was involved in disputes regarding access to required medication. In accepting a request from the United States for a review panel, the WTO was set to delve into the issue of Brazil's intention with regard to the domestic production of antiretroviral drugs. However, in June 2001, the United States withdrew the complaint and request for a panel.

In September 2003, a presidential decree was signed which allowed generic drugs to be imported.[184] The ability to import a generic variant considerably increases the strength of Brazil's bargaining position in negotiations with the patent-holding pharmaceutical companies. Following this, in January 2004, the Brazilian National AIDS Program announced that successful negotiations had been completed to obtain a wide-ranging package of antiretroviral drugs at significantly reduced prices, with savings estimated at around US$100 million for 2004 alone.[185]

Within Brazil, free and universal access to HAART has been available since 1996. HAART is provided for symptomatic, positive persons without reference to their viral load count and to asymptomatic persons with CD4 counts of below 200/mm^3. HAART is considered for asymptomatic persons with a CD4 count of between 200/mm3 and 350/mm^3 on a case by case basis.[186] From a figure below 40,000 in 1997, reportedly 180,000 of the estimated 600,000 positive persons in 2006 were receiving the necessary treatment.[187]

Specifically, the per person per year ("PPPY") prices for many of the relevant patented drugs, such as efavirenz, nelfinavir, tenofovir and lopinavir 133mg with ritonavir 33mg declined by over 50% between the

184 Decreto Número 4.830. *DiárioOficial da União*. September 5, 2003;:1

185 Kaiser Network.org, *Brazil's National STD/AIDS Programme Announces Largest Drug Price Reduction Deals in Five Years*. Menlo Park, California: Henry J. Kaiser Family Foundation; January 20, 2004. available at http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=21751&dr_cat=1

186 Nunn, Amy S., Fonseca et al *Evolution Of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment* (2007) 11 PLOS Medicine 1.

187 National STD and AIDS Program of Brazil, *Sau´de assina acordo para reduzir prec ode anti-retroviral. Brasilia*, 2007, available at http://www.saberviver.org.br/index.php?s_op=anti-retroviral

period 2001-2005. In particular, the decline from the first offer PPPYs in 2003 for Nelfinavir and Efavirenz are at 69% and 77% respectfully.[188]

Whilst Brazil is held up as a good example of a public health HIV/AIDS programme, it cannot be said that there no longer exists a constant struggle to maintain low prices. Between 2003 and 2005, the cost of HAART supply increased by a factor of 2.5. In isolating the period 2004-2005, while the number of patients increased by a mere 8%, the cost of HAART doubled.[189] In this period, there has also been an increase in the standard of care , including the replacement of locally produced generic drugs with newer patented antiretroviral drugs.

Whereas the price of generic antiretroviral drugs in the international marketplace have fallen substantially, such prices in Brazil have constantly risen since 2003. One explanation for this is the fact that 75% of the cost involved in the production of a drug stems from the active pharmaceutical ingredients.[190] The domestic, public, drug production facilities in Brazil do not conduct chemical synthesis to produce active pharmaceutical ingredients ("APIs"), and most of the necessary supply is met by imports from China and India. Nonetheless, the cost increases in generic production are still small in scale, compared with the savings accumulated in the price reductions which have been attained in negotiations for the patented medication. The recent decision by Brazil to issue a compulsory licence and import generic efarvirenz signals that Brazil intends to continue its bullish bargaining stance regarding drug pricing.

Brazil has managed to attain such price reductions only through taking international political risks and threatening compulsory licensing. Brazil has trodden a path that others must follow if similar prices are to be obtained for their own countries. Thailand, for example, has done so and issued compulsory licences for antiretroviral drugs in 2006 and 2007.[191]

188 Note 187, *supra*

189 Ibid.

190 Pinheiro, E, A. et al. (2006) 'Examining the production costs of antiretroviral drugs'(2006) 20 *AIDS* 1745–52.

191 Included within these drugs were lopinavir and efavirenz.

CHAPTER 8

Patent Law and Access to Medicines

Background and significance

Several interrelated factors determine access to essential drugs, including drugs to treat HIV and opportunistic infections. Among them are cost, supply management, drug selection, legislation and regulation, manufacturing constraints, and research and development decisions.[192] Since effective treatment for HIV/AIDS is relatively new, most of the antiretroviral drugs created to treat AIDS remain under patent.[193] Since patent protection prevents generic competition, it leads to an increase in the price of HIV/AIDS treatment and thereby limits availability and accessibility.

A patent is a set of exclusive rights granted by a state to a patentee (the inventor or assignee) for a fixed period of time in exchange for the regulated, public disclosure of certain details of a device, method, process or composition of matter (known as an invention) which is new, inventive, and useful or industrially applicable. A patent provides the right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, usually 20 years from the filing date. A patent is, in effect, a limited property right that the Government offers to inventors in exchange for their agreement to share the details of their inventions with the public. Like any other property right, it may be sold, licensed, mortgaged, assigned or transferred, given away, or simply abandoned. To put it differently, it is a monopoly right created in favour of somebody with the sanction of law. The are two kinds of patents: (i) process patent and (ii) product patents. A process patent gives the owner exclusive rights over the manufacturing process, not the product itself. In other words, anyone can make and sell the particular product, provided they use a different process to make it. A

192 Ibid.
193 Ibid.

product patent prevents others from manufacturing, selling, distributing or importing the patented product – even versions produced through different processes – without the patent holder's authorisation. A patent is a set of exclusive rights granted by a state to a patentee (the inventor or assignee) for a fixed period of time in exchange for the regulated, public disclosure of certain details of a device, method, process or composition of matter (known as an invention) which is new, inventive, and useful or industrially applicable. A patent provides the right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, usually 20 years from the filing date. A patent is, in effect, a limited property right that the Government offers to inventors in exchange for their agreement to share the details of their inventions with the public. Like any other property right, it may be sold, licensed, mortgaged, assigned or transferred, given away, or simply abandoned. To put it differently, it is a monopoly right created in favour of somebody with the sanction of law. The are two kinds of patents: (i) process patent and (ii) product patents. A process patent gives the owner exclusive rights over the manufacturing process, not the product itself. In other words, anyone can make and sell the particular product, provided they use a different process to make it. A product patent prevents others from manufacturing, selling, distributing or importing the patented product – even versions produced through different processes – without the patent holder's authorisation.

HIV/AIDS is quite recent in medical history, and therefore most of the drugs created especially to treat HIV infection are proprietary i.e. still under patent.[194] This renders treatment less affordable than it would be if the required drugs had generic alternatives available. As patent protection allows exclusive rights to an invention and prevents generic competition, it is one of the causes of limited availability and affordability of drugs in certain parts of the world. As for drugs to treat or prevent opportunistic infections and malignancies, a number of anti-infective agents needed by people living with HIV/AIDS also remain under patent in many countries. Therefore, the question whether a drug is under patent protection is of significant importance for drug procurement.[195] India has had a vibrant generic industry since 1970, when it amended its existing patent Act

194 See, for example, http://www.ipaustralia.gov.au/patents/what_index.shtml for further details

195 Ibid.

to disallow patent protection for pharmaceutical products.[196] India has been and remains the producer of choice for medications in most developing countries, producing medicines of assured quality that meet all international standards, at the lowest costs and highest volumes.[197] In recent times, the most striking success of Indian pharmaceutical companies has been their ability to provide access to HIV/AIDS drugs at an affordable price.

Indian Patent Legislation and Generic Drug Manufacture in India

The 1970 Indian Patent Act (1970 IPA) prohibited patent protection for pharmaceuticals, food or agrochemical products, reduced validity periods of process patents from 20 years to 7 years, and introduced "automatic licensing." In addition to this landmark patent legislation, the Indian Government placed import restrictions and tariffs on critical inputs and finished drug formulations coming from other countries.[198] The Government also strictly enforced ratio requirements, where imports of bulk drugs had to be matched by purchases from domestic sources at a certain fixed ratio. The national Government also passed the 1970 Drugs Price Control Order, introducing price controls making it less profitable for foreign firms to sell patented drugs in the Indian market.[199] With support from such a strong and favourable regulatory environment, the Indian pharmaceutical industry exploded with finished formulations and APIs post-1970. By 2004, the domestic pharmaceutical market in India was worth approximately $4.3 billion, three-quarters of which was supplied by Indian firms.

By 1991, Indian companies accounted for 70% of bulk drugs and 80% of formulations produced in the country, quite a feat considering India's large market size.[200] Generic ARV drugs manufactured in India were also prevalent in the treatment of HIV/AIDS in the developing world. As of 2005, India supplied 22% of the world's generic drugs and a significant

196 Baker, Brook K. "*India's 2005 Patent Act: Death by Patent or Universal Access to Second- and Future-Generation ARVs?*" Background paper. Health Gap; Global Access Project, 2005

197 Ibid.

198 Jean O. Lanjouw, "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'" Economic Growth Center Discussion Paper No. 775 (New Haven: Yale University, 1997) 4.

199 Ibid.

200 Ibid. at 4

portion of the vaccines made for the developing world.[201] However, with India's adoption of the TRIPS Agreement, and the consequent amendments to the 1970 IPA, the generic manufacturing industry was placed in a period of transition, threatening access to treatment.

India adopted the TRIPS Agreement in 1995, but was given a ten-year window to reform its intellectual property regime, culminating in the 2005 (Amendments) Indian Patent Act (2005 IPA). The amendments implemented a number of changes to India's patent system including, most notably, product patents. Under the 2005 IPA, inventors are now able to patent the pharmaceutical products they develop, and prevent generic manufacturers from producing or selling these drugs without license for the duration of the patent (usually 20 years).[202] Two categories of generic products remain legal in the Indian market: (i) generic copies of products already off-patent in regulated markets; and (ii) generic versions of products patented before 1995. These two categories comprise over 90% of the products on the Indian market, including many first-line ARV drugs.[203] Whilst many of the ARV drugs currently produced in India were developed prior to 1995, and will therefore escape this legislation, it has significant implications for the availability and affordability of any drugs produced after that date.

Generic versions of products patented after 2005 are generally considered illegal, and not allowed in the Indian market. These new patent monopolies in India could prevent the generic production of newer, more expensive combinations of ARV drugs ("second-line treatment") needed for PLHAs that become resistant to "first-line" treatment. Though patent-protected ARV drugs are relatively few in number, they still represent a very large percentage of health and treatment budgets. For example, of the 14 ARV drugs on the Brazilian National AIDS Programme, three new single-source products accounted for 63% of the total programme costs in 2003.[204] The provisions in the 2005 IPA have clearly spelled out the status of generic versions of drugs invented before 1995 and after

201 Cheri Grace, "*A Briefing Paper for DFID: Update on China and India and Access to Medicines*," (London: DFID Health Resource Centre, 2005) 8.

202 Sorcha O'Carroll, "Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya," Online: Accessed on 7 July 2008, http://www.law.utoronto.ca 1.

203 Cheri Grace, "*The Effect of Changing Intellectual Property on Pharmaceutical Indnstry Prospects in India and China: Considerations for Access to Medicines*," (London: DFID Health Systems Resource Centre, 2004) 31.

204 http://content.healthaffairs.org/cgi/content/full/23/5/279-a

2005. What about drugs that are invented and/or patented within the ten-year transition window?

Drugs patented between 1995 and 2005 (during the ten-year TRIPS implementation period) were placed in a "mailbox" for review for patent approval in 2005. If a patent had been granted for the drug in another WTO member country, its owners could be granted Exclusive Marketing Rights (EMR) until a decision was made on the patent application. EMR give the patent owner the exclusive right to sell or distribute the product in India for a period of five years, or until the patent application is accepted or rejected, whichever comes first. EMR offer rights very similar to that of patents, and in many ways, contain even stronger monopoly provisions, as they are easier to obtain, and do not have to go through the same rigorous examination and opposition process that a patent does.

Under section 11A(7) of the 2005 IPA, a product "in the mailbox" can continue to be commercialised, even if the branded original has been granted patent protection, provided that the domestic generic manufacturers pay a "reasonable royalty" to the patent holders. However, the patent-holder shall only be entitled to receive reasonable royalties from such enterprises which have made a significant investment, were producing and marketing the concerned product prior to January 1, 2005, and continue to manufacture the product covered by the patent.[205] If a manufacturer is able to meet these requirements, a pharmaceutical company/patent owner would be unable to bring an infringement claim against the generic company, but only demand reasonable royalties. Notwithstanding this provision, the amendments made in the 2005 IPA strengthened the protection of intellectual property rights, especially with regards to pharmaceutical products. What are the implications of this for Access to Treatment?

The 2005 Indian Patent Act and Access to Treatment

Proponents of TRIPS argued that the 2005 Amendments to the IPA would allow local Indian companies to increase foreign investment, receive a transfer of technology and focus research and development on local diseases, thereby enhancing access to treatment. However, the evidence has shown otherwise, with Indian generic manufacturers increasingly turning their attention towards more lucrative foreign markets and the diseases of developed countries. Overall, evidence shows that

205 *The Patents (Amendment) Act, 2005*, The Gazette of India, Part II, Section 1, (2005) s. 11A (7).

implementation of stringent patent rights in developing countries has had a negative impact on access to treatment, especially for PLHAs.

The treatment process for PLHA is usually complex, often involving multiple drugs in a process called "combination therapy." Under this treatment procedure, all the drugs have to be taken in combination in order to maximise effectiveness (see Chapter 2 for further detail). The use of multiple drug therapies is generally considered superior to single-drug therapies, because it increases the chance of reducing development of drug-resistant strains of HIV by cancelling out mutations against other drugs. Lack of access to one drug in a combination therapy therefore precludes effective treatment for a large number of PLHA. A case in point is the WHO-recommended fixed-dose combination of d4T/3TC/NVP, a combination of generic ARV drugs. According to the humanitarian medical aid agency Médecins Sans Frontières (MSF), this generic triple combination therapy costs 26 times less than using the originator's triple therapy of TDF+ddI+LPV/r.[206] Despite the fact that NVP and d4T are off-patent as individual drugs, Glaxo-Smith-Kline's (GSK) patent on the ARV 3TC blocked the availability of the simplest and most affordable AIDS treatment available worldwide.[207]

Lack of access to one drug in a triple combination therapy encourages Governments to consider below-optimum combinations as the therapeutic choice, leading to potentially disastrous consequences. For example, the exclusivity afforded by intellectual property protection made 3TC unavailable in China, and the Chinese Government consequently promoted a therapeutic treatment regimen that excluded 3TC.[208] It is clear that access to proper antiretroviral treatment is limited due to the high costs associated with patented ARV drugs. This is exacerbated by the fact that ARV drugs as a class experience a high speed of product development, due to emerging resistance. Drugs in this class have little therapeutic competition with older drugs that essentially become ineffective due to viral resistance.[209] With new waves of ARV drugs being produced to combat resistance, access to proper treatment will only worsen as these new drugs are subject to patent protection and the monopoly pricing power associated with it. There are, however, some safeguards within the 2005 IPA (such as compulsory licensing) that prevent complete patent monopolies in order to ensure a minimum level of access to treatment.

206 Note 209, *supra*, at 19
207 Ibid., at 18
208 Ibid.
209 Ibid., at 20

The Price is Right: Exporting Generic Drugs to the Developing World

With the growth of the Indian pharmaceutical industry in the 1970s, Indian generic manufacturers developed cheaper versions of various patented drugs and moved aggressively into the global market once the international patents expired.[210] As the Indian generic manufacturing industry expanded rapidly during this time, it became a major international supplier of drugs to countries where these products could be marketed legally because they had not been patented locally, usually developing countries.[211] With overall production of $7.3 billion (finished product domestic consumption plus exports), Indian firms produce approximately 1.5% of the global pharmaceutical market of $480 billion. This small share in value terms belies the importance of the Indian industry in volume terms, estimated at more than 20% of global consumption.[212]

The export statistics further illustrate the importance of the Indian pharmaceutical industry to developing countries around the world. In 2003, 40% of India's finished products and 60% of India's APIs (active pharmaceutical ingredients), by value, were exported. Out of these exports, 44%, by value, went to highly regulated markets (i.e. USA, Europe, Japan and Australia), while the other 56% went to less regulated markets, a category which applies to all developing countries.[213] These export trends illustrate the comparative advantage of India's generic manufacturing industry: lower costs leading to lower prices for pharmaceutical products.

In 2004, India's drug prices were among the lowest in the world, even in purchasing power parity (PPP) terms. In a study comparing the prices between India and other countries where patent protection exists, the evidence indicates that in some cases drugs are up to 41 times more expensive in countries with patent protection.[214] For example, a study by an International Monetary Fund (IMF) economist reported that drug

210 Nilesh Zacharias & Sandeep Farias, "Patents and the Indian Pharmaceutical Industry," Business Briefing: Pharmagenerics (2003) 2

211 John H. Barton, "TRIPS and the Global Pharmaceutical Market," 23:3 Health Affairs (Stanford: Project Hope, 2004) 147.

212 Note 208, *supra*, at 13

213 Ibid., at 14

214 K. Balasubramaniam, "*Access to Medicines and Public Policy Under TRIPS*," Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability, eds. Christophe Bellmann, Graham Dutfield and Ricardo Melendez-Ortiz (London: Earthscan, 2003) 137

prices in Malaysia, where patent protection exists, were from 20 percent to 760 percent higher than in India.[215] According to the MSF pricing chart below, ARV drugs from leading Indian generic companies such as Cipla and Hetero were among the lowest, if not the lowest, in terms of pricing in the leading global pharmaceutical markets. Further information available from Médecins Sans Frontières set out of Table 9 below[216] shows that, whilst there has been some evening out of prices amongst manufacturers of generic drugs, Indian manufacturers remain among the cheapest.

Table 9: Prices of ARV Drugs (Proprietary vs. Generic) in Leading Global Pharmaceutical Markets

	Proprietary		Generics			
Drugs	Wholesale price in the United States	Cheapest proprietary offer*	GPO (Thailand)	Brazilian Generics	Cipla (India)	Hetero (India)
Nucleoside reverse transcriptase inhibitor						
Stavudine	3577	55	158	197	40	47
Lamivudine	3285	232	678	248	170	98
Zidovudine	5721	NA	395	328	307	290
Zidovudine+lamivudine combination	7154	730	1006	396	480	285
Didanosine	2628	292	537	715	584	NA
Non nucleoside reverse transcriptase inhibitor						
Nevirapine	3838	486	948	246	280	202
Efavirenz	4758	580	NA	NA	NA	1179
Protease inhibitor						
Indinavir	6016	600	NA	1840	1340	2300

Source: MSF Pricing Report [5], Wall Street Journal [13], UNAIDS, generic manufacturers. NA: Not available. *Restrictions and lack of transparency apply to most proprietary offers; stavudine and didanosine, sold in seven African countries, made public the terms of its offer for efavirenz and indinavir (see http://www.msfcampaign.org/press/030704.html, accessed 16 July 2001). †Figures for July 2001.

Source: Tido von Schoen Angerer, David Wilson, Nathan Ford and Toby Kasper, "Access and Activism: The Ethics of Antiretroviral Therapy in Developing Countries," 15:5 AIDS 2001 (London: Lippincott, Williams & Wilkins, 2001) S85.

The spreadsheet at Appendix B compares the price of common ARV drugs in various countries, broken down into a public/private sector dichotomy. With the data available, the chart shows that India is among the least expensive provider of generic ARV drugs around the world. With such a significant price differential, Indian generic manufacturers strategically serve the high-volume, low-price segment of the pharmaceutical market.

There are also benefits associated with the Indian generic manufacturing industry that extend beyond the price of the generic drug itself. In addition to direct supply, Indian generic drugs have an important indirect effect on the competitiveness of the marketplace for ARV drugs. Competition from generic drugs has been credited with reducing the cost of ARV

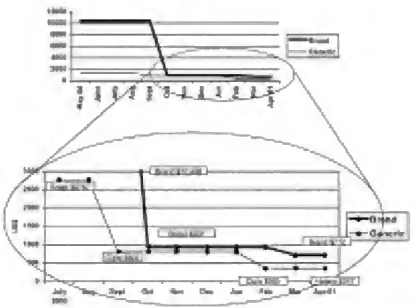
215 Ibid.

216 http://infochangeindia.org/index2.php?option=com_content&do_pdf=1&id=6071

drugs for a single patient from as much as $15,000 USD per year to as little as $150 USD per year.[217] This downward trend of ARV prices has occurred throughout the world. In Brazil, ARV prices came down by 82% within 5 years after Brazil initiated local generic production – based primarily on API supply from India – facilitating free universal treatment to Brazilians who needed it.[218]

Another meaningful indicator of this phenomenon would be the effects of "generic entry" on the prices of drugs coming off patent. For a graphical representation on the effects of generic competition on the prices of drugs, please see Figure 3 below:

Figure 3: Price Trends of Triple Combination Therapy
With Increased Generic Competition



The effects of generic composition: sample AIDS triple combination at lowest world prices (stavudine, lamivudine, and nevirapine). The price of AIDS triple therapy for developing countries fell from US$ 10000 per patient per year to US$ 350 in 1 year due to generic competition.

Source: Tido von Schoen Angerer, David Wilson, Nathan Ford and Toby Kasper, "Access and Activism: The Ethics of Antiretroviral Therapy in Developing Countries," 15:5 AIDS 2001 (London: Lippincott, Williams & Wilkins, 2001) S86.

A New Direction for Access to Treatment in the Post-TRIPS World

With the introduction of product patents on all drugs invented after January 1, 2005, Indian generic companies could no longer "reverse

217 Note 207, *supra*, at 1
218 Note 208, *supra*, at 15

engineer" any drug that was patented elsewhere in the world. With a lack of product-related research and development (the focus of the Indian generic industry was on process-related research and development), much of the Indian generic industry was consolidated into a smaller number of companies. To compensate for loss of revenue, many Indian pharmaceutical companies expanded their generic drug exports, either as suppliers or through joint venture agreements with foreign companies, usually in developed countries.[219] More and more Indian companies have increased their emphasis on exporting to the more profitable regulated markets, as evidenced by the large concentration of U.S. Food and Drug Administration (FDA)-approved manufacturing plants in India – more than any other country in the world besides the U.S. itself.[220]

Even with this trend towards producing drugs for developed countries and "first world diseases," there is still flexibility within the present intellectual property regime to ensure access to treatment in developing countries.

Patent Opposition: A Key Instrument Within the Framework of TRIPS

With the adoption of TRIPS, it was imperative that member countries implemented a proper procedure to scrutinise the thousands of patent applications submitted to patent offices every year. The 1970 IPA provided a detailed pre-grant opposition procedure to avoid wrongful claims by scrutinising claims before a patent was granted. Over a period not exceeding 18 months, the complete specifications of the product were to be made open for public inspection, and any interested person could oppose the grant of the patent on certain specified grounds.[221] However, Section 25 of the 2005 IPA has diluted these provisions into a primarily post-grant opposition procedure. There are 11 grounds on which a patent can be opposed, but this can only be done within one year after the patent has already been granted. India's pre-grant opposition procedure is restricted to only two grounds: 1) non-compliance with patentability requirements (including novelty, inventive step and industrial applicability); and 2) non-disclosure or wrongful disclosure of genetic resources or traditional knowledge.[222] With limited pre-grant

219 Ibid., at 17

220 Ibid., at 7-8.

221 Chaudhuri, Saudip, *"TRIPS and Changes in Pharmaceutical Patent Regime in India"* Working Paper No 535, January 2005, India Institute of Management, Calcutta, at page 13

222 Ibid.

opposition mechanisms, there exists the possibility that patents could be granted without extensive examination and scrutiny by the public. Once an application satisfies all the requirements of the 2005 IPA, a patent is granted expeditiously and published in the official gazette. It is only then that the patent is opened up for public inspection, whereas this process previously took place before the granting of the patent.

Despite these limitations, there have been a number of successful patent opposition cases that have been pivotal to enhancing access to treatment in India.

An opposition brought in respect of Nevirapine syrup set an important precedent for all future ARV patent oppositions in India. The Indian Network for People Living with HIV/AIDS (INP+) and the Positive Women's Network (PWN) filed a pre-grant opposition for the patenting of Nevirapine syrup, a paediatric drug used to treat positive children who are unable to swallow conventional ARV drugs. On June 11, 2008, the Indian Patent Office rejected the patent application of the German pharmaceutical company Boehringer Ingelheim, based on both technical and public health grounds. Specifically, the patent office found that the syrup formulation of Nevirapine was merely a new form of a known drug that was first invented in 1989, well before the TRIPS/2005 IPA patent cut-off date of 1995. This decision affirmed the interpretation that India's current patent law does not consider improvements or new forms of known medicines to be patentable.[223] More importantly, the ruling called into question the practice of "evergreening," where pharmaceutical companies make minor variations to existing medicines in order to extend their patent monopolies for as long as possible. In the aftermath of this landmark ruling, there is renewed hope for the ongoing patent oppositions regarding other ARV drugs in India such as Atazanavir, Efavirenz, Valganciclovir and Tenofovir, among others.

Another important victory was achieved in August 2006 when GlaxoSmithKline (GSK) announced that it would withdraw its patent application for the ARV Combivir, a critical fixed-dose combination of two existing drugs – zidovudine and lamivudine. The withdrawal was in response to a patent opposition filed by INP+ and the Manipur Network of Positive People, who claimed the drug lacked novelty, was not inventive and was therefore not patentable. GSK has since pulled out patent

223 Medecins Sans Frontieres, "*Pre-Grant Opposition Victory in India*," Campaign for Access to Essential Medicines, Online: Accessed on 23 July 2008 h ttp://www.accessmed-msf.org/main/access-patents/pre-grant-opposition-victory-in-india/

applications for two other ARV drugs in India – Abacavir and Trizivir – much to the relief of HIV patients and generic firms across the country.[224]

These two India rulings demonstrate the potential for pre-grant and/or post-grant opposition procedures to enhance access to treatment by controlling patent monopolies, which invariably drive drug prices up. The Governments of developing countries should partner with civil society to ensure the patent opposition procedure is open, transparent, accessible, and geared towards the interests of public health first and foremost.

Looking Back to the Road Ahead

When it passed the 1970 IPA, it was clear that the Indian Government's policy was geared towards protection of public health and the expansion of the Indian generic manufacturing industry. Evidence shows this strategy was hugely successful in increasing the number of generic drugs available, lowering prices of ARV drugs (either directly or indirectly through competition in the marketplace) and enhancing access to treatment, especially for developing countries that lacked the manufacturing capacity to produce their own generic drugs. However, with India's admission into the WTO and the adoption of TRIPS, the country's pioneering intellectual property regime was harmonised with that of the rest of the developed world. Product patents were allowed, and large multinational pharmaceutical corporations were able to monopolise ownership of ARV drugs, driving prices up. The Indian generic manufacturing industry is now in a phase of transition, and we need a new strategy for ensuring access to treatment in the post-TRIPS world. The TRIPS Agreement itself contains flexible mechanisms for balancing access to treatment with the preservation of intellectual property rights, such as compulsory licensing, parallel importation and patent opposition procedures. However, these instruments will inherently be limited in enhancing access to treatment because they still operate within the framework of TRIPS and the dominant intellectual property regime. The Indian Government is at a crossroads – it must ask itself whether the best interests of the country lie inside or outside the global TRIPS framework. The lives of millions of PLHA in the developing world depend on the answer.

224 Khomba Singh, "*GSK Drops Claims on Two AIDS Medicines*," The Economic Times, 7 December 2007, Online: Accessed on 23 July 2008 h ttp://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/GSK_drops_claims_on_two_aids_medicines/articleshow/2602468.cms

Appendix A

Note: Bold name is the generic name, Italic name is the brand/trade name and the name in parenthesis is the short-hand acronym used to refer to the generic drug.

Class, Drug, Originator

NRTI abacavir (ABC) *Ziagen* Glaxo Smith Kline (GSK)
NRTI didanosine (ddI) *Videx* Bristol-Myers Squibb (BMS)
NRTI didanosine (ddI) *Videx EC* BMS
NRTI emtricitabine (FTC) *Emtriva*l Gilead
NRTI lamivudine (3TC) *Epivir* GSK
NRTI stavudine (d4T) *Zerit* BMS
NRTI zidovudine (AZT or ZDV) *Retrovir* GSK
NtRTI tenofovir disoproxil fumarate (TDF) *Viread* Gilead
NNRTIs efavirenz (EFV) *Stocrin* 200 mg Merck, BMS owns rights in N. America & 5 European countries as *Sustiva*
NNRTIs efavirenz (EFZ) *Stocrin* 600 mg Merck
NNRTIs nevirapine (NVP) *Viramune* Boehringer Ingelheim (BI)
Protease inhibitors atazanavir (ATV) *Reyataz* BMS
Protease inhibitors indinavir (IVD) *Crixivan* Merck
Protease inhibitors **nelfinavir** (NFV) *Viracept* Pfizer, but Roche has international contract
Protease inhibitors lopinavir-ritonavir (LPV/r) *Kaletra* Abbott
Protease inhibitors saquinavir (SQV) *Fortovase or Invirase* Roche
Protease inhibitors ritonavir *Norvir* Abbott

Co-formulated combinations, Originator(s)

tenofovir/ efavirenz/ emtricitabine (TDF/EFZ/FTC) *(In development)* Gilead & BMS (with Merck)
tenofovir/emtricitabine (TDF/FTC) *Truvada* Gilead
lamivudine / zidovudine (3TC/AZT) *Combivir* GSK
abacavir/ lamivudine / zidovudine (ABC/ 3TC/AZT) *Trivizir* GSK
lamivudine / stavudine /nevirapine (3TC/D4T/NVP) GSK/BMS/BI [no originator product – made by generic companies]
zidovudine/lamivudine/nevirapine (AZT/3TC/NVP) GSK/BI [no originator product – made by generic companies]
stavudine/ lamivudine (D4T/3TC) BMS/GSK [no originator product – made by generic companies]

Appendix B

Comparative Prices of ARV Drugs in the Public and Private Sector									
Drugs	U.S.	Zimbabwe	U.K.	France	Thailand	Norway	Sweden	Kenya	Columbia
Zidovudine (AZT), 100mg caps (PVT.)	$1.69	$0.91	$1.881	$1.31		$1.83	$1.71	$1.21	
Zidovudine (AZT), 100mg caps (PUBLIC)				$1.29	$0.30				$0.67
Didanosine (ddI), 100mg tabs (PVT.)	$1.82	$1.34	$2.22	$1.77		$2.10	$2.33	$2.15	
Didanosine (ddI), 100mg tabs (PUBLIC)					$0.65				$0.85
Zalcitabine (ddC), 0.75mg tabs (PVT.)	$1.88	$2.00	$2.29	$1.94		$2.40	$2.01		
Zalcitabine (ddC), 0.75mg tabs (PUBLIC)				$1.77					$1.41
Stavudine (d4T), 40mg caps (PVT.)	$4.56	$4.85	$4.66	$3.68		$5.73	$4.93	$5.04	
Stavudine (d4T), 40mg caps (PUBLIC)					$0.38				$2.40
Abacavir (ABC), 300mg tabs (PVT.)	$5.82	NA	$6.02			$6.03	$5.25		
Abacavir (ABC), 300mg tabs (PUBLIC)				$5.80					NA
Lamivudine (3TC), 150mg tabs (PVT.)	$4.33	$3.52	$4.13	$2.92		$3.67	$2.75	$2.93	
Lamivudine (3TC), 150mg tabs (PUBLIC)				$2.30					$1.73
Nevirapine (NVP), 200mg tabs (PVT.)	$4.25	$5.18	$4.25	Still in negotiation		$4.53	$3.80	$8.73	
Nevirapine (NVP), 200mg tabs (PUBLIC)									$4.31
Delavirdine (DLV), 100mg tabs (PVT.)	$0.67	NA	NA	NA					
Delavirdine (DLV), 100mg tabs (PUBLIC)				NA					$0.46
Efavirenez (EFV), 100mg tabs (PVT.)	$2.19	NA	$1.97	Still in negotiation		$2.13	$1.87		
Efavirenez (EFV), 100mg tabs (PUBLIC)									$3.34
Saquinavir (SQV), 200mg caps (PVT.)	$1.09	$1.74	$0.83						
Saquinavir (SQV), 200mg caps (PUBLIC)				$0.79					$1.15
Ritonavir (RTV), 100mg caps (PVT.)	$1.86	$1.26	$3.18						
Ritonavir (RTV), 100mg caps (PUBLIC)				$0.91					$0.99
Indinavir (IDV), 400mg caps (PVT.)	$2.58	$2.99	$1.83	$1.59					
Indinavir (IDV), 400mg caps (PUBLIC)				$1.57					$1.84
Nelfinavir(NFV), 250mg tabs (PVT.)	$2.16	$1.61	$1.62	$1.40					
Nelfinavir(NFV), 250mg tabs (PUBLIC)				$1.29					$1.54

Annexure 1

Antiretroviral drugs supplied by the National AIDS Control Organisation to ART Centres nationwide, and available free of charge to those in need[225]

S.No.	ARV Drug Combination Containing Ingredients	No. of Tablets
1	Two drugs combination tablets containing Stavudine 40mg plus Lamivudine 150mg	6120
2	Two drugs combination tablets containing Stavudine 30mg plus Lamivudine 150mg	680
3	Two drugs combination tablets containing Zidovudine 300mg plus Lamivudine 150mg	10200
4	Three drugs combination tablets containing Stavudine 30mg plus Lamivudine 150mg plus Nevirapine 200mg	20160
5	Three drugs combination tablets containing Stavudine 40mg plus Lamivudine 150mg plus Nevirapine 200mg	2240
6	Three drugs combination tablets containing Zidovudine 300mg plus Lamivudine 150mg plus Nevirapine 200mg	33600
7	Tablet Nevirapine 200mg	1200
8	Tablet Effaviranz 600mg	7300

225 http://www.nacoonline.org/upload/Care%20&%20Treatment/Operational%20Guidelines%20for%20ART%20Centers%20-%20March%202007.pdf

Annexure 2

Antiretroviral regimen and dosages recommended by the National AIDS Control Organisation[226]

Generic name	Dose	
Nucleoside RTIs		
Abacavir (ABC)	300 mg twice daily or 600 mg once daily	
Zidovudine (AZT)	300 mg twice daily	
Emtricitabine (FTC)	200 mg once daily	
Didanosine (ddI)	<60 kg: 400 mg once daily >60 kg: 250 mg once daily	
Lamivudine (3TC)	150 mg twice daily or 300 mg once daily	
Stavudine (d4T)	30 mg twice daily	
Nucleotide RTI		
Tenofovir	300 mg once daily	
Non-nucleoside RTIs		
Efavirenz (EFV)	600 mg once daily	
Nevirapine (NVP)	200 mg once daily for 14 days lead in dose followed by 200 mg twice daily	
Protease inhibitors		
Atazanavir/ritonavir (ATV/r)	300 mg/100 mg once daily	
Fosamprenavir/ritonavir (FPV/r)	700mg/100 mg twice daily	
Indinavir/ritonavir (IDV/r)	800 mg/100 mg twice daily	
Lopinavir/ritonavir (LPV/r)	Capsule Lopinavir 133 mg + ritonavir 33 mg	Three capsules twice daily (or 400/100 mg twice daily) Four capsules once daily when combined with EFV or NVP (534/133 mg twice daily)
	Tablet (heat stable formulation) Lopinavir 200mg + ritonavir 50mg	Treatment naive patients Two tablets twice daily (or one tablet of co-administration with ATV or NVP (400/100 mg twice daily) Treatment experienced patients Three tablets twice daily when combined with EFV or NVP (600/150 mg twice daily)
Nelfinavir (NFV)	1250 mg twice daily	
Saquinavir/ritonavir (SQV/r)	1000/100 mg twice daily	

1. d4T dose should be adjusted when co-administered with tenofovir. If weight <60 kg, give d4T at 25mg twice daily. If weight >60 kg, give d4T at 30 mg twice daily.
2. See TB section for TB specific dose modification in hepatotoxicity.

226 http://www.nacoonline.org/upload/Publication/Treatment%20Care%20and%20support/Antiretroviral%20Therapy%20Guidelines%20for%20HIV-Infected%20Adults%20and%20Adolescents%20Including%20Post-exposure.pdf

Annexure 3

Antiretroviral regimen and dosages recommended by the World Health Organisation[227]

Nucleoside reverse transcriptase inhibitors (NsRTI)	
Abacavir (ABC)	tablet 300 mg, oral solution 100 mg/5 ml
Didanosine (ddI)	tablet 25 mg, 100 mg, 150 mg, 200 mg
Lamivudine (3TC)	tablet 150 mg, oral solution 50 mg/5 ml
Stavudine (d4T)	capsule 15 mg, 20 mg, 30 mg, 40 mg, oral solution 5 mg/ml
Zidovudine (ZDV or AZT)	capsule 100 mg, 250 mg, 300 mg; injection 10 mg/ml in 20 ml vial; oral solution 50 mg/5 ml
Non nucleoside reverse transcriptase inhibitors (NNRTI)	
Efavirenz (EFV or EFZ)	capsule 50 mg, 100 mg, 200 mg
Nevirapine (NVP)	tablet 200 mg, oral suspension 50 mg/5 ml
Protease inhibitors	
Indinavir (IDV)	capsule 100 mg, 200 mg, 333 mg, 400 mg
Ritonavir (RTV, r) [a]	capsule 100 mg, oral solution 400 mg/5 ml
Lopinavir + ritonavir (LPV/r)	capsule 133.3 mg + 33 mg, oral solution 400 mg/5 ml + 100 mg/5 ml
Nelfinavir (NFV)	tablet 250 mg, powder 50 mg/g
Saquinavir (SQV)	capsule gel filled 200 mg

[a]Ritonavir is recommended for use in combination with indinavir, lopinavir and saquinavir as a booster and not as a drug in its own right.

227 http://www.searo.who.int/en/Section10/Section18/Section356/Section408_2215.htm

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